
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.

Instructions for Use

USS™ Universal Spine System

Universal Spine System family consists of pedicle screw systems designed for use with either Ø 5.0mm (i.e., USS II, USS II Polyaxial, USS II Polyaxial Perforated and USS II Ilio-Sacral) or Ø 6.0mm 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 Ø 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.

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 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



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. 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.
- Be aware of vulnerable patient populations (such as pregnant patients, patients who are not medically optimized, or patients who may be at increased risk of complications from prone positioning) and carefully consider the potential risks associated with using this medical device in such groups.
- Warning: Special considerations should be taken with patients with known allergies or hypersensitivities to implant materials.

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 \varnothing 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 \varnothing 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 \varnothing 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 bicortically, 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 patient's 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 patient's 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 \varnothing 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 Ø 5.0 mm or Ø 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 Ø 6.0 mm
- Side opening pedicle screw (Ø 4.0, 5.0, 6.0, 7.0 mm) with sleeve and nut
- Pedicle hook
- Screw for pedicle hook (Ø 3.2 mm)
- Lamina hook
- Angled lamina hook
- Rod connector
- Connectors for rod
- Parallel connector and extension connector
- Cross-link clamp for rod
- Rod Ø 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 Ø 6.0 mm
- Single side opening pedicle screw (Ø 4.2, 5.0, 6.0, 7.0 mm),
- Sleeve and nut
- Pedicle hook
- Screw for pedicle hook (Ø 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 Ø 3.5 mm for cross-link

USS II Spine System

The USS II System consists of a set of implants including

- Rod (Ø 5.0 mm and 6.0 mm)
- Pedicle screw with dual opening and dual-core diameter (Ø 4.2, 5.2, 6.2, 7.0, 8.0 and 9.0 mm)
- Sleeve and nut
- Pedicle hook
- Screw for pedicle hook (Ø 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 Ø 3.5 mm for cross-link
- Fixation ring
- Anterior vertebral body screw (Ø 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 (Ø 5.0 mm and 6.0 mm), dual-core pedicle screw (Ø 4.2, 5.2, 6.2, 7.0, 8.0 mm), cancellous bone screw (Ø 6.2, 7.0, 8.0 mm), polyaxial 3-D head, sleeve and nut.

USS II Polyaxial Perforated

This system consists of rod (Ø 5.0 mm and 6.0 mm), USS II Polyaxial Perforated pedicle screw (Ø 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 (Ø 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 (Ø 5.0 mm)
- Pedicle screws (Ø 4.2, 5.0, 6.0, 7.0 mm) with dual side-openings
- Sleeve and nut
- Pedicle hooks
- Screw for pedicle hooks (Ø 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 Instruments.

USS Universal Spine System

314.060	Holding Sleeve
314.070	Screwdriver, hexagonal, small, 2.5 mm, w/Groove
315.190	Drill Bit Ø 2.0 mm, L 100/75 mm
319.060	Depth Gauge f/Screws Ø 1.5 to 2.0 mm
319.100	Depth Gauge f/Screws Ø 4.5 to 6.5 mm
387.060	Handle f/Drill Sleeve 2.0
388.130	Socket Wrench 11.0 mm, w/L-Handle
388.140	Socket Wrench 6.0mm, w/straight Handle
388.360	USS Holding Sleeve, f/No. 314.070
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 335mm, f/Pedicle Screws
388.440	Holding Forceps w/broad tip, L 290mm
388.450	Holding Forceps f/USS Rods Ø 3.5/4.5 mm, L 295 mm
388.490	USS Rod Crimping Pliers
388.500	USS Rod Introd. Pliers, f/Impl. w/side-opening
388.501	Counter Torque f/USS Rod Introduction Pliers
388.502	USS Sleeve Pusher, f/No. 388.500
388.510	USS Pedicle Feeler, L 300 mm
388.520	USS Lamina Feeler, L 300 mm
388.538	Pedicle Probe Ø 2.8 mm, L 230 mm
388.540	Pedicle Probe Ø 3.8 mm, L 230 mm
388.550	Pedicle Awl Ø 4.0 mm, L 230 mm
388.581	USS Drill Sleeve 2.0
388.610	USS Hook and Screwholder
388.630	Hook Positioner f/USS
388.640	USS Handle, f/Nos. 388.330, 388.370 + 388.610
388.691	USS Pusher, f/Angled USS Washers
388.750	USS Rod Cutting and Bending Device
388.870	Trial Rod Ø 6.0 mm, L 150 mm
388.880	Trial Rod Ø 6.0 mm, L 400 mm
388.910	USS Bending Iron, left
388.920	USS Bending Iron, right
388.940	Rod Pusher f/USS Rods Ø 6.0 mm
388.960	Bending Pliers w/Rolls f/USS Rods

USS II Spine System

03.602.042	Torque-limiting Handle, 12 Nm
03.620.021	Template f/Transverse Connectors low profile
314.070	Screwdriver, hexagonal, small, 2.5 mm, w/Groove
315.190	Drill Bit Ø 2.0mm, L 100/75 mm
319.060	Depth Gauge f/Screws Ø 1.5 to 2.0 mm
357.789	Length Indicator f/Pedicle Screws Ø 4.2–9.0 mm
385.807	Insertor f/Angled Washers Ø 6.0–8.0 mm
387.060	Handle f/Drill Sleeve 2.0
388.143	Socket Wrench 5.0 mm, w/T-Handle
388.145	Socket Wrench, hexagonal, 5.0 mm w/T-Handle
388.159	Socket Wrench, w/straight handle
388.161	Sleeve Positioner f/USS-II
388.163	Holding Sleeve f/No. 388.159
388.338	Screwdriver 4.0mm w/T-Handle
388.360	USS Holding Sleeve, f/No. 314.070
388.363	Holding Sleeve w/Catches, f/No. 314.070
388.381	Holding Sleeve f/Fillister Head Screws
388.410	Spreader Forceps f/Pedicle Screws, L 330 mm
388.413	Spreader Forceps f/USS Small Stature/Paediatric
388.422	Compression Forceps, L 335mm, f/Pedicle Screws
388.424	Compression Forceps f/USS Small Stature/Paediatric
388.440	Holding Forceps w/broad tip, L 290mm
388.441	Holding Forceps f/USS SmStat/Paed Rods Ø 5.0 mm
388.450	Holding Forceps f/USS Rods Ø 3.5/4.5 mm, L 295 mm
388.508	Rod Introduction Pliers f/Rods Ø 6.0 mm
388.510	USS Pedicle Feeler, L 300 mm
388.512	USS-II Pedicle Feeler, L 300 mm, f/small hooks
388.520	USS Lamina Feeler, L 300 mm
388.521	USS Small Stature/Paediatric Lamina Feeler
388.530	USS Chisel, width 9mm
388.538	Pedicle Probe Ø 2.8 mm, L 230 mm
388.539	Pedicle Probe Ø 4.8 mm, L 230 mm
388.540	Pedicle Probe Ø 3.8 mm, L 230 mm
388.545	Feeler f/Screw Channel, straight
388.546	Feeler f/Screw Channel, curved
388.550	Pedicle Awl Ø 4.0 mm, L 230 mm
388.551	Pedicle Awl Ø 3.0 mm, L 230 mm
388.581	USS Drill Sleeve 2.0
388.582	Sleeve Pusher
388.584	Socket Wrench f/twelve point nut
388.608	Pedicle Marker USS-II, w/spherical bulges
388.609	Pedicle Marker USS-II, w/long bulges
388.612	USS Hook and Screwholder
388.615	Counter Torque f/Rod Introduction Pliers
388.622	Handle f/USS Hook and Screwholder
388.632	Hook Positioner f/USS-II
388.750	USS Rod Cutting and Bending Device
388.870	Trial Rod Ø 6.0 mm, L 150 mm
388.880	Trial Rod Ø 6.0 mm, L 400 mm
388.906	Trial Rod Ø 5.0 mm, L 150 mm
388.907	Trial Rod Ø 5.0 mm, L 500 mm
388.910	USS Bending Iron, left
388.911	USS SmStat/Paed Bending Iron f/Rods Ø 5.0 mm
388.920	USS Bending Iron, right
388.922	USS SmStat/Paed Bending Iron f/Rods Ø 5.0 mm
388.960	Bending Pliers w/Rolls f/USS Rods
388.961	Bending Pliers, w/Bend Radius Adjustment

USS II Polyaxial Spine System

03.602.042	Torque-limiting Handle, 12 Nm
03.603.108	Remobilization Tool f/Lotus/USS-II-Polyaxial
03.607.000	Reamer f/USS-II-Polyaxial
03.607.001	Screwdriver, bihexagonal 3.0 mm, w/T-Handle
03.607.002	Screwdriver Shaft, L from 70 mm onwards
03.607.003	USS-II Polyaxial Holding Sleeve
03.607.004	USS-II Polyaxial Positioning Pliers
03.607.005	USS-II Polyaxial Screwholder
03.607.006	USS-II Polyaxial Handle, f/No. 03.607.005
03.607.007	Positioner, f/No. 03.607.005
03.607.008	Socket Wrench, bihexagonal 11.0 mm, self-holding
03.607.009	USS-II Polyaxial Rod Introduction Pliers
03.607.013	Stopping Sleeve f/Remobilizing w/o Rod
03.607.014	Hollow Reamer Ø 12.6 mm f/USS-II-Polyaxial
388.143	Socket Wrench 5.0 mm, w/T-Handle
388.410	Spreader Forceps f/Pedicle Screws, L 330 mm
388.440	Holding Forceps w/broad tip, L 290 mm
388.502	USS Sleeve Pusher, f/No. 388.500
388.538	Pedicle Probe Ø 2.8 mm, L 230 mm
388.539	Pedicle Probe Ø 4.8 mm, L 230 mm
388.540	Pedicle Probe Ø 3.8 mm, L 230 mm
388.550	Pedicle Awl Ø 4.0 mm, L 230 mm
388.551	Pedicle Awl Ø 3.0 mm, L 230 mm
388.584	Socket Wrench f/twelve point nut
388.615	Counter Torque f/Rod Introduction Pliers
388.960	Bending Pliers w/Rolls f/USS Rods

USS II Ilio-Sacral Spine System

03.607.000	Reamer f/USS-II-Polyaxial
03.607.001	Screwdriver, bihexagonal 3.0 mm, w/T-Handle
03.607.002	Screwdriver Shaft, L from 70 mm onwards
03.607.003	USS-II Polyaxial Holding Sleeve
03.607.005	USS-II Polyaxial Screwholder
03.607.006	USS-II Polyaxial Handle, f/No. 03.607.005
03.621.011	Clamp Holder
03.621.012	Socket Wrench, cannulated, w/straight handle
03.621.031	Template f/Iliac Connector, short
03.621.032	Template f/Iliac Connector, medium
03.621.033	Template f/Iliac Connector, long
314.070	Screwdriver, hexagonal, small, 2.5mm, w/Groove
319.011	Length Indicator f/Pedicle Screws
388.143	Socket Wrench 5.0 mm, w/T-Handle
388.410	Spreader Forceps f/Pedicle Screws, L 330mm
388.539	Pedicle Probe Ø 4.8 mm, L 230 mm
388.540	Pedicle Probe Ø 3.8 mm, L 230 mm
388.584	Socket Wrench f/twelve point nut
388.615	Counter Torque f/Rod Introduction Pliers
388.622	Handle f/USS Hook and Screwholder

USS II Polyaxial Perforated

02.606.001	Kirschner Wire Ø 1.6 mm w/trocar tip, L 480 mm
02.606.003	Kirschner Wire Ø 1.6 mm w/o trocar tip, L 480 mm
02.648.001	Cleaning Stylet f/perforated Pedicle Screws
03.600.030	Pedicle Awl Ø 5.6 mm, cannulated
03.600.031	Pedicle Probe Ø 5.0 mm, cannulated
03.600.032	Pedicle Awl Ø 3.8 mm, cannulated
03.600.033	Pedicle Probe Ø 3.5 mm, cannulated
03.606.020	Trocar Ø 1.6 mm
03.606.021	Trocar Holder, f/No. 03.606.020
03.607.100	USS-II-Polyaxial Reamer f/perforated Screws
03.607.101	Screwdriver Shaft Stardrive, T25, cannulated
03.607.103	USS-II Polyaxial Holding Sleeve f/perf. Ped. Scr.
03.620.206	Tap, cannulated, f/Pedicle Screws Ø 6.0 mm

03.620.207	Tap, cannulated, f/Pedicle Screws Ø 7.0 mm
03.620.226	Protection Sleeve 8.2/6.3, f/No. 03.620.206
03.620.227	Protection Sleeve 9.2/7.3, f/No. 03.620.207
03.702.2155	Vertecem V+ Syringe Kit
03.702.224.025	Needle Adapter Kit w/Luer-Lock
07.702.0165	Vertecem V+ Cement Kit
07.702.216.025	Simple Adapter f/perforated Pedicle Screws
388.538	Pedicle Probe Ø 2.8 mm, L 230 mm
388.539	Pedicle Probe Ø 4.8 mm, L 230 mm
388.540	Pedicle Probe Ø 3.8 mm, L 230 mm
388.550	Pedicle Awl Ø 4.0 mm, L 230 mm
388.654	Ratchet w/Handle
392.040	Handle f/Kirschner Wires Ø 0.6 to 1.6 mm

USS Low Profile Spine System

310.190	Drill Bit Ø 2.0 mm, L 100/75 mm
314.070	Screwdriver, hexagonal, small, 2.5 mm, w/Groove
319.060	Depth Gauge f/Screws Ø 1.5 to 2.0 mm
357.789	Length Indicator f/Pedicle Screws Ø 4.2–9.0 mm
388.130	Socket Wrench 11.0 mm, w/L-Handle
388.140	Socket Wrench 6.0 mm, w/straight Handle
388.360	USS Holding Sleeve, f/No. 314.070
388.381	Holding Sleeve f/Fillister Head Screws
388.410	Spreader Forceps f/Pedicle Screws, L 330 mm
388.422	Compression Forceps, L 335 mm, f/Pedicle Screws
388.440	Holding Forceps w/broad tip, L 290 mm
388.490	USS Rod Crimping Pliers
388.500	USS Rod Introd. Pliers, f/Impl. w/side-opening
388.501	Counter Torque f/USS Rod Introduction Pliers
388.502	USS Sleeve Pusher, f/No. 388.500
388.510	USS Pedicle Feeler, L 300 mm
388.520	USS Lamina Feeler, L 300 mm
388.521	USS Small Stature/Paediatric Lamina Feeler
388.538	Pedicle Probe Ø 2.8 mm, L 230 mm
388.539	Pedicle Probe Ø 4.8 mm, L 230 mm
388.540	Pedicle Probe Ø 3.8 mm, L 230 mm
388.545	Feeler f/Screw Channel, straight
388.546	Feeler f/Screw Channel, curved
388.550	Pedicle Awl Ø 4.0 mm, L 230 mm
388.551	Pedicle Awl Ø 3.0 mm, L 230 mm
388.581	USS Drill Sleeve 2.0
388.616	USS Low Profile Hook and Screwholder
388.640	USS Handle, f/Nos. 388.330, 388.370 + 388.610
388.641	USS Low Profile Sleeve, f/No. 388.640
388.642	USS Low Profile Hook Positioner
388.643	USS Low Profile Counter Torque Instrument
388.663	USS Low Profile Socket Wrench Ø 11.0 mm, L 300 mm
388.870	Trial Rod Ø 6.0 mm, L 150 mm
388.880	Trial Rod Ø 6.0 mm, L 400 mm
388.910	USS Bending Iron, left
388.920	USS Bending Iron, right
388.960	Bending Pliers w/Rolls f/USS Rods
498.911	Fixation Ring f/Rods Ø 6.0 mm

USS Small Stature / Paediatric Spine System

314.070	Screwdriver, hexagonal, small, 2.5 mm, w/Groove
315.190	Drill Bit Ø 2.0 mm, L 100/75 mm
319.060	Depth Gauge f/Screws Ø 1.5 to 2.0 mm
357.789	Length Indicator f/Pedicle Screws Ø 4.2–9.0 mm
385.807	Insertor f/Angled Washers Ø 6.0–8.0 mm
387.060	Handle f/Drill Sleeve 2.0
388.143	Socket Wrench 5.0 mm, w/T-Handle
388.335	Screwdriver, hexagonal, Ø 4.0 mm, L 375 mm
388.337	Screwdriver Shaft 4.0, hexagonal, L 265 mm

388.338	Screwdriver 4.0 mm w/T-Handle
388.360	USS Holding Sleeve, f/No. 314.070
388.380	USS Holding Sleeve
388.381	Holding Sleeve f/Fillister Head Screws
388.413	Spreader Forceps f/USS Small Stature/Paediatric
388.424	Compression Forceps f/USS Small Stature/Paediatric
388.441	Holding Forceps f/USS SmStat/Paed Rods Ø 5.0 mm
388.503	USS SmStature/Paediatric Rod Introduction Pliers
388.511	USS Small Stature/Paediatric Pedicle Feeler
388.521	USS Small Stature/Paediatric Lamina Feeler
388.530	USS Chisel, width 9 mm
388.538	Pedicle Probe Ø 2.8 mm, L 230 mm
388.539	Pedicle Probe Ø 4.8 mm, L 230 mm
388.540	Pedicle Probe Ø 3.8 mm, L 230 mm
388.545	Feeler f/Screw Channel, straight
388.546	Feeler f/Screw Channel, curved
388.550	Pedicle Awl Ø 4.0 mm, L 230 mm
388.551	Pedicle Awl Ø 3.0 mm, L 230 mm
388.581	USS Drill Sleeve 2.0
388.582	Sleeve Pusher
388.583	Sleeve Positioner f/USS Small Stature/Paediatric
388.584	Socket Wrench f/twelve point nut
388.612	USS Hook and Screwholder
388.615	Counter Torque f/Rod Introduction Pliers
388.622	Handle f/USS Hook and Screwholder
388.631	Hook Positioner f/USS Small Stature/Paediatric
388.906	Trial Rod Ø 5.0 mm, L 150 mm
388.907	Trial Rod Ø 5.0 mm, L 500 mm
388.911	USS SmStat/Paed Bending Iron f/Rods Ø 5.0 mm
388.922	USS SmStat/Paed Bending Iron f/Rods Ø 5.0 mm
388.941	Rod Pusher f/USS SmStat/Paediatric Rods Ø 5.0 mm
388.961	Bending Pliers, w/Bend Radius Adjustment
498.021	USS Small Stature/Paediatric Sleeve, toothed
498.022	USS Small Stature/Paediatric Nut
498.909	Fixation Ring f/Rods Ø 5.0 mm

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.

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

The Universal Spine System implant is intended for permanent implantation and is not intended for 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 bihexagonal 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.

Special Operating Instructions

USS Universal Spine System

Picking up implants

- The side-opening pedicle screws have the same head as the hooks. Therefore, the following handling instructions apply to both pedicle screws and hooks (called side-opening implants in the following).

Attach handle to stick

- Attach the USS handle to the hook and screw holder, the "stick".

Pick up implant

- Connect the side-opening implant to the stick by rotating the cogwheel of the handle.

Release handle from stick

- Insert the implant. To release the handle from the stick, press the release mechanism on top of the handle.

Pedicle screw positioning (posterior instrumentation)

Open pedicle and determine screw length

- Use the pedicle awl to open the cortex of the pedicle to a depth of 10 mm. Continue opening the pedicle using the USS pedicle probe \varnothing 3.8 mm with markings at 30, 40 and 50 mm.
- Determine the length of the pedicle screw using the depth gauge for screws.
- For \varnothing 4.0 mm or \varnothing 5.0 mm pedicle screws, use the pedicle probe \varnothing 2.8 mm.

Insert pedicle screw into pedicle

- Pick up a side-opening pedicle screw as described in step “Picking up implants”.
- If a rod connector is needed, align the screw head by turning it 90°. The opening has to be perpendicular to the rod.
- Insert the pedicle screw into the prepared pedicle until the screw head is well seated. To disassemble the stick from the handle, press the button on the handle.

Pedicle screw positioning with washers (anterior instrumentation only)

- Flat and angled washers can be used with anterior fixation constructs to distribute the force of the screw over the bone. The angled washers form a fixed angle with the screw.

Open pedicle and determine screw length

- Determine the entry point for the screw, preferably at the junction of the pedicle and the vertebral body.
- Use the pedicle awl to prepare the screw hole, directing it perpendicularly to the contralateral side. Enlarge the screw hole using the USS pedicle probe, until it penetrates the contralateral cortex.
- Determine the length of the pedicle screw using the depth gauge for screws. The actual length of the screw is chosen 5 mm longer than measured in order to enable the positioning of a washer.

Insert screw and flat washer

- Place flat washers with the convex side down onto the concavity of the vertebral body.
- Pick up a side-opening pedicle screw as described in step “Picking up implants”. Insert the pedicle screw into the prepared vertebral body until the screw head is well seated. To disassemble the stick from the handle, press the button on the handle.

Insert angled washer

- Pick up screw and washer: Slide an appropriate-size pedicle screw into a washer and pick it up with a stick. Insert the screw until the washer slightly touches the bone surface. Leave a space of 8–10 mm between the angled washer and the screw for the USS pusher.
- Place pusher onto stick: Pull the cannulated guide of the pusher backwards until the ringmark appears. Place the tip of the pusher onto the washer and the cannulation of the pusher over the stick. Push down the cannulated guide to lock the stick in place.
- Insert screw and washer: Tap onto the end of the pusher to introduce the angled washer into the bone. When tapping the pusher, the force is transmitted to the angled washer and not to the screw. Once the washer is firmly seated, remove the pusher. Using the USS handle, insert the screw further until the screw head is well seated.

Pedicle hook positioning

- The USS pedicle hooks can be anchored in the pedicle with a single \varnothing 3.2 mm USS screw for pedicle hook.

Prepare seat for pedicle hook

- Prepare the pedicle using the pedicle feeler. Place the pedicle feeler between the inferior and superior facet joints.
- To facilitate the insertion of the pedicle feeler, a small portion of the inferior facet is removed with an osteotome. The pedicle feeler has six lines on the blade. When the last line is reached, sufficient bone has been removed to accommodate the hook around the pedicle.
- Check the optimal position of the pedicle feeler by moving it laterally and cranially.
- Remove the pedicle feeler.

Position pedicle hook

- Pick up a pedicle hook from the tray with the hook and screw holder as described in step “Picking up implants”.
- Use a front-opening hook if a rod connector is needed.
- Insert the USS hook positioner into the screw hole of the hook and ease the pedicle hook into the previously prepared seat. Check if the pedicle hook is snug around the pedicle by axial loading of the hook positioner and also by pushing laterally. The pedicle hook should not move. Gently tap the hook positioner with a hammer to firmly seat the hook.
- Remove the hook positioner and the USS handle. The stick remains attached to the hook.

Drill hole for \varnothing 3.2 mm screw

- To anchor the pedicle hook to the pedicle screw, a \varnothing 3.2 mm cortical screw can be inserted through the hole at the back of the pedicle hook.
- Use a three-fluted drill bit \varnothing 2.0 mm together with the USS drill sleeve 2.0 and an oscillating drill to drill the screw hole. The drill sleeve consists of two components, the drill sleeve and the handle. These two components must be screwed together before use. Advance the tip of the drill until it passes through the vertebral endplate.

Determine screw length

- Remove the drill sleeve and determine the depth with the depth gauge for screws \varnothing 1.5 to 2.0 mm.

Insert \varnothing 3.2 mm screw

- Pick up an appropriate length USS screw for pedicle hooks using the holding sleeve and screwdriver and insert it into the previously prepared drill hole. The pedicle hook is now attached to the pedicle and the endplate.

Lamina hook positioning

Prepare seat for lamina hook

- The lamina hook can be placed around either the superior or inferior portion of the lamina. Prepare the seat for the lamina hook using the lamina feeler. To ensure a good seating of the hook, carefully remove the ligamentum flavum and a small portion of the lamina with a rongeur.
- Remove the lamina feeler.

Position lamina hook

- Pick up an appropriate-size lamina hook from the tray with the hook and screw holder as described in step “Pedicle screw positioning with washers (anterior instrumentation only) – Insert angled washer”.
- Use a front-opening hook if a rod connector is needed.
- Insert the hook positioner into the screw hole of the hook and ease the lamina hook into the previously prepared seat. The inferior part of the lamina hook must fit snugly to the lamina.
- Remove the hook positioner and the handle. The stick remains attached to the hook.

Angled lamina hook positioning

Prepare seat for angled lamina hook

- Remove the soft tissue of the transverse process. Place the lamina feeler around the transverse process elevating the soft tissue attachment from the anterior portion of the transverse process.
- Remove the lamina feeler.

Position angled lamina hook

- Pick up an appropriate-size angled lamina hook from the tray with the hook and screw holder as described in step “Picking up implants”.
- Use a front-opening hook if a rod connector is needed.
- Insert the hook positioner into the screw hole of the hook and ease the angled lamina hook into the previously prepared seat.
- Remove the hook positioner and the handle. The stick remains attached to the hook.

Rod contouring

- Use the trial rod to determine the rod contour and length.
- Contour the rod using either the bending pliers with rolls or the USS bending irons.
- If necessary, the construct can be extended by connecting two rods with a parallel or extension connector.
- Hook/screw offset: Anatomical conditions sometimes result in the implants not being aligned in a straight line. The screws and hooks have a 4-mm offset. If the implants are not aligned during rod insertion it may be necessary to rotate the screw by 180 degrees or choose a different hook (i.e., left or right side opening).

Introducing rods into side-opening implants

- Use USS rod introduction pliers (“persuader”)
 - Occasionally, a rod cannot easily be introduced into a dual-opening implant because of the distance between the rod and the implant.
 - With the rod introduction pliers, the persuader, the side-opening implant can be lifted and pulled towards the rod.

Mount sleeve pusher onto persuader

- Place the sleeve pusher onto the cylinder of the persuader. Place a sleeve onto the cylinder so that the short leg of the sleeve faces in direction of the rod.

Place persuader onto implants

- Slide the cylinder of the persuader over the hook and screw holder and the limb of the pliers on the rod.

Attach support for rod introduction pliers

- Slide the support for rod introduction pliers over the protruding end of the stick and click the stopping lever into place. The support for rod introduction pliers is used to prevent rotation of the side-opening implant.
- Alternatively, the holding forceps can be used.

Bring rod towards side-opening implant

- Gently close the persuader to bring the side-opening implant towards the rod.

Lift implant up towards rod

- Place the spreader forceps between the support for rod introduction pliers and the cylinder. Slowly open the spreader to bring the implant up towards the rod. When the opening of the implant is opposite the rod, close the persuader to engage the rod.
- Remove the support for rod introduction pliers.

Place sleeve over implant and rod

- Push the sleeve pusher down the cylinder and place the sleeve over the rod and implant.

Place sleeve using rod pusher (optional)

- If the sleeve cannot be engaged, place the rod pusher onto the sleeve and gently tap the sleeve into place.

Attach rod to implant

- Remove the persuader. Pick up a nut, place it over the stick and attach it loosely to the implant.
- (Alternative) Using rod crimping pliers:
 - Use the rod crimping pliers to ease the rod into the side-opening implants.
 - Pick up a sleeve and nut with the USS handle and place them over the construct.

Distraction or compression of adjacent implants

- Using the spreader or compression forceps
 - Once the rod has been introduced and loosely attached to the implant, carry out distraction or compression if necessary.
 - Before tightening the nut of the implant, use the spreader forceps for distraction or the compression forceps for compression.
- Using the fixation ring (optional)
 - If the two implants are placed too far from each other, use the fixation ring. Place the small hexagonal screwdriver with the holding sleeve onto the fixation ring and place it next to the screw. During this procedure, the screw to rod connection has to be loose. Carry out distraction or compression.
 - Remove the fixation ring and tighten the nut of the implant.
- (Alternative) Using the holding forceps for rods
 - Instead of using the fixation ring, place the holding forceps for rods next to a screw and carry out distraction or compression.

Locking side-opening implants to a rod

- The \varnothing 6.0 mm rod is held in place with a sleeve and nut. If the sleeve has not been placed while introducing the rod into the implant using the persuader as described in step “Introducing rods into side-opening implants” proceed as follows:

Pick up sleeve and nut

- Pick up a sleeve and a nut with the USS handle.

Place sleeve and nut over implant

- Place the handle over the stick and press the top of the handle to release the sleeve and nut.
- The sleeve has a long and a short leg. The short leg slides over the open side of the implant and has a small mark on the top for identification.

Tighten nut

- Tighten the construction with the nut using the socket wrench 11.0 mm with L-handle. Use the socket wrench 6.0 mm mounted on the stick to counteract torque.

Connecting a rod to an implant with closed rod connectors

- Rod connectors can be used to bridge distances between rod and implant. When using rod connectors, frontal opening hooks must be used or the pedicle screw turned by 90°. Rod connector bars are introduced into the implant at a right angle to the rod.
- Closed rod connectors can be used at either end of the USS construct. They can be added at the end of a procedure.

Select closed rod connector

- Select the appropriate length of the closed rod connector bar. Introduce the small hexagonal screwdriver and the USS holding sleeve into the set screw of the rod connector clamp.

Place rod connector onto rod and into implant

- Slide the closed rod connector onto the rod and introduce the rod connector bar into the front-opening hook or screw. If necessary, use the rod crimping pliers or the persuader, as described in step “Introducing rods into side-opening implants”.

Secure rod connector

- Tighten the set screw of the rod connector clamp. Place the sleeve and nut onto the side-opening implant and tighten it using the socket wrench 11.0 mm with L-handle and the socket wrench 6.0 mm mounted on the stick to counteract torque.

Connecting two rods with cross-link clamps

- Cross-link clamps are designed to connect the two longitudinal rods.

Mount first cross-link clamp

- Assemble the small hexagonal screwdriver and the holding sleeve with catches. Pull back the holding sleeve. To pick up the pre-assembled cross-link clamp, insert the hexagonal screwdriver into the set screw of the clamp, push down the holding sleeve and clip the catches onto the sleeve of the pre-assembled clamp. Pull the holding sleeve back slightly, place the clamp onto the rod and release the holding sleeve.

Introduce cross-link rod

- The design of the cross-link sleeve with its two recesses on top allows the cross-link rod to be angled up to $\pm 20^\circ$ as necessary.
- Determine the appropriate length of the \varnothing 3.5 mm cross-link rod. If necessary, cut to length using the USS rod cutting and bending device.
- Hold the clamp with the small hexagonal screwdriver and introduce the \varnothing 3.5 mm cross-link rod through the hole in the cross-link clamp. If necessary, use the holding forceps 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 of step “Mount first cross-link clamp” of this section for the second clamp on the opposite rod. Introduce the \varnothing 3.5 mm cross-link rod through the second clamp, so that it protrudes by 0.5 cm beyond the clamp. Tighten the set screw with the small hexagonal screwdriver.

Distraction cross-link assembly (optional)

- Loosen one of the set screws. Place the holding forceps next to the clamp and use the spreader forceps to apply distraction. Tighten the set screw of the clamp with the small hexagonal screwdriver.

USS II Spine System

Implant handling using the stick

- The screws with dual openings have the same head as the pedicle, lamina and transverse process hooks. The following handling tips therefore apply both to the pedicle screws and anterior vertebral body screws, and to all three types of hooks (referred to as “implants” in surgical procedural steps of “USS II Spine System”).

Attach handle to stick

- Press the knurled release button on the top end of the handle and simultaneously push the USS hook and screwholder, known as the “stick”, into the handle.

Pick up implant

- Insert stick into implant. Turn release button in a clockwise direction and pick up the implant.

Release handle from stick

- Insert the implant. Press the release button on the handle to detach the handle from the stick.

Insert pedicle screw

Open pedicle and determine screw length

- Use one of the awls to open the pedicle cortex to a depth of 10 mm. Open the pedicle further using one of the USS pedicle probes with markings at 30, 40 and 50 mm.

\varnothing Screw (mm)	Pedicle Awl	Pedicle Probe
4.2	388.551	388.538 (\varnothing 2.8 mm)
5.2, 6.2	388.550	388.540 (\varnothing 3.8 mm)
7.0	388.550	388.539 (\varnothing 4.8 mm)

- Determine the length of the pedicle screw with the length indicator for pedicle screws.

Probe pedicle channel

- Use the straight or curved feeler to probe the pedicle screw channel to check the wall for perforations.

Optional: Use of pedicle markers

- Use a pedicle marker with spherical bulges and/or a pedicle marker with long bulges to verify the position and alignment radiographically. The bulges show the depth at 10 mm intervals. The use of pedicle markers with bulges of two different shapes facilitates differentiation between the left and right pedicle.

Insert pedicle screw into pedicle

- Pick up the pedicle screw as described in step “Implant handling using the stick”. Insert the pedicle screw into the prepared pedicle until the screw head is well seated and one of the openings points towards the rod that is to be subsequently inserted. Press the release button to detach the handle from the stick.
- If using a rod connector, align the screw head such that one of the openings is perpendicular to the rod.

Position pedicle hook

- The USS II pedicle hooks can be anchored in the pedicle with a single \varnothing 3.2 mm USS screw for pedicle hook.

Prepare seat for pedicle hook

- Prepare the pedicle with the USS pedicle feeler. Place the pedicle feeler between the inferior and superior articular facets.
- To facilitate the insertion of the pedicle hook, remove a small portion of the inferior facet with an osteotome. There are six marks on the pedicle feeler; once the last one has been reached, sufficient bone has been removed to position the hook about the pedicle.
- Move the feeler in a lateral and cranial direction to check for the desired position.
- Remove the pedicle feeler.

Position pedicle hook

- Pick up the pedicle hook as described in step “Implant handling using the stick”.
- Use a front-opening hook if a rod connector is required to connect the hook to the longitudinal rod.
- Insert the hook positioner for USS II into the screw hole of the pedicle hook and move the hook into the prepared position.
- Ensure that the pedicle hook is snug around the pedicle by pushing the hook positioner axially and laterally. The pedicle hook should not move.
- Gently tap the hook positioner with a hammer to firmly seat the hook.
- Remove the hook positioner and the handle. The stick remains attached to the hook.

Drill hole for screw \varnothing 3.2 mm and determine the screw length

- To anchor the pedicle hook to the pedicle the \varnothing 3.2 mm screw can be inserted through the hole in the back of the hook.
- Use the 3-flute drill bit \varnothing 2.0 mm with the USS drill sleeve 2.0 and an oscillating drill to drill the screw hole. The drill sleeve consists of two parts, the sleeve and the handle. These two components must be screwed together before use.
- Remove the drill sleeve and determine the depth of the hole using the depth gauge.

Insert screw \varnothing 3.2 mm

- Pick up a suitable length USS screw for pedicle hook with the holding sleeve and the hexagonal screwdriver and insert it in the pre-drilled hole. The pedicle hook is now attached to the pedicle.

Position lamina hook

Prepare seat for lamina hook

- The lamina hook can be placed around either the superior or inferior portion of the lamina. Prepare the seat for the lamina hook using a lamina feeler. Carefully remove the ligamentum flavum and a small portion of the lamina with a rongeur to ensure good seating of the lamina hook.
- Remove the lamina feeler.

Position lamina hook

- Pick up the lamina hook as described in step “Implant handling using the stick”.
- Use a front-opening hook if a rod connector is needed.
- Insert the hook positioner for USS II in the positioning hole of the hook and move the lamina hook into the prepared position. The inferior part of the lamina hook must fit snugly with the lamina.
- Remove the hook positioner and the handle. The stick remains attached to the hook.

Angled lamina hook positioning

Prepare seat for angled lamina hook

- Remove the soft tissue from the transverse process. Place a lamina feeler round the transverse process and thus detach the soft tissue attachment points from the anterior part of the transverse process.
- Remove the lamina feeler.

Angled lamina hook positioning

- Pick up the angled lamina hook as described in step “Implant handling using the stick”.
- Use a front-opening hook if a rod connector is needed.
- Insert the hook positioner for USS II in the positioning hole of the hook and move the angled lamina hook into the prepared position.
- Remove the hook positioner and the handle. The stick remains attached to the hook.

Rod contouring

- Use a trial rod for USS rods (for 5.0 mm or 6.0 mm rods) to determine the shape and length of the rod to be inserted.
- Use the bending pliers with rolls for USS rods or the USS bending iron to bend the rod.
- Regarding the hook/screw offset: Anatomical conditions sometimes result in the implants not being aligned in a straight line so that the rod cannot be inserted into all the implants from the same side. The USS II pedicle screws and hooks have offset heads and the dual opening design allows for insertion of the rod to either side of the pedicle screws and hooks.

Locking implants to rods – Option A: Place sleeve and nut consecutively

- The rod is fixed with a sleeve and a nut.
- When using a 5 mm rod, sleeve 499.239/ 499.239S must be used; when using a 6 mm rod, sleeve 499.302/ 499.302S must be used.

Pick up and locate sleeve with sleeve positioner

- Place the sleeve pusher on the sleeve positioner for USS II. Pick up an appropriate sleeve: the shorter leg of the sleeve pusher must be above the narrow-lipped side of the sleeve.
- Slide the sleeve positioner over the stick and place it on the implant.
- Press down on the sleeve pusher to place the sleeve on the implant/rod. Lift the sleeve pusher again. The sleeve remains on the implant/rod.
- If the sleeve cannot be placed on the implant/rod then tap lightly on the sleeve pusher. The hook positioner for USS II can be used for this purpose by placing it in the round indentation on the handle of the sleeve pusher.

Place nut on implant

- Use the socket wrench for twelve point nut, with L-handle to pick up the nut from the loading station and screw it on to the implant thread (screw or hook).

Tighten the nut finger-tight

- Tighten the nut using the socket wrench for twelve point nut with L-handle. The socket wrench for the counter torque is spring loaded and can be pressed downwards continuously with the left hand using the T-handle.
- To tighten the nut further, lift the L-handle of the socket wrench with the right hand and engage it again.
- If using a 6 mm rod, a few threads will remain visible on the nut.

Locking implants to rods - Option B: Place sleeve and nut in a single operation

Position sleeve and nut

- Place holding sleeve on the socket wrench with straight handle.
- To pick up a sleeve and nut, first place a nut on the sleeve and then fit the socket wrench from above.
- Push the holding sleeve downwards to fix the sleeve in position. The sleeve can only be picked up in a specific position. One leg of the holding sleeve is marked with an arrow. This must be located above the narrow-lipped side of the sleeve.
- Position the socket wrench/holding sleeve connection above the implant (screw or hook). Place sleeve and nut together using the socket wrench handle.

Tighten the nut finger-tight

- Tighten the nut using the socket wrench for twelve point nut with L-handle. The socket wrench for the counter torque is spring-loaded and can be pressed downwards continuously with the left hand using the T-handle.
- To tighten the nut further, lift the L-handle of the socket wrench with the right hand and engage it again.
- If using a 6 mm rod, a few threads will remain visible on the nut.

Locking implants to rods – Option C: Rod introduction pliers (“persuader”)

- Use rod introduction pliers (“persuader”)
 - Occasionally, a rod cannot easily be introduced into a dual-opening implant because of the distance between the rod and the implant.
 - With the rod introduction pliers for USS II, the persuader, dual-opening implants can be lifted and drawn on to the rod. Rod and implant are fixed directly with the sleeve.
 - When using a 5 mm rod, sleeve 499.239/ 499.239S must be used, when using a 6 mm rod, sleeve 499.302/ 499.302S must be used.

Mount sleeve pusher onto persuader

- Fix the sleeve pusher on to the cylinder of the persuader. Use the attached sleeve pusher to pick up a sleeve from the loading station. The shorter leg of the sleeve pusher must be above the narrow-lipped side of the sleeve. The handle of the sleeve pusher must be located on the side of the persuader with the arrow.

Place persuader on implant

- Slide the cylinder of the persuader on the stick and the leg of the pliers on the rod.

Attach counter torque for rod introduction pliers

- The counter torque/support for rod introduction pliers serves as a locking device when lifting the implants and allows the implants to be rotated.
- Slide the counter torque for rod introduction pliers on to the projecting end of the stick and pull the lever at the same time. The fork-shaped opening of the counter torque must point upwards. Release the lever so that the fork of the counter torque engages in the hexagonal socket of the stick.

Bring rod towards dual-opening implant

- Bring the spreader forceps to the stick between the counter torque and persuader. Slowly open the spreader to bring the implant up towards the rod. Once the implant opening has reached the level of the rod, slowly close the persuader to insert the rod.
- Remove the counter torque/support for rod introduction pliers.

Place sleeve over implant and rod

- Push the sleeve pusher down the cylinder to place the sleeve over the rod and implant. Retract the sleeve pusher. The sleeve remains on the implant/rod.
- If the sleeve cannot be readily placed in position, ensure that the lateral opening of the screw or hook is properly aligned on the rod. If necessary, a light tap on the sleeve pusher may help. The hook positioner for USS II may be used for this purpose: place it in the round indentation on the handle of the sleeve pusher.

Attach implant to rod

- Remove the persuader. Pick up a nut with the socket wrench for twelve point nut, allow it to slide over the stick and screw it loosely on to the implant.

Final tightening of nut

- Tighten the nut firmly with the socket wrench for twelve point nut with L-handle. Insert the socket wrench 5.0 mm with T-handle into the socket wrench for twelve point nut and pass the two together over the stick. The socket wrench 5.0 mm must engage in the hexagonal socket of the stick. The stick serves to apply counter-torque. The socket wrench is spring-loaded and can be pushed down continuously with the left hand on the T-handle. To tighten the nut further, lift the L-handle of the socket wrench with the right hand and engage it again.
- If the stick has already been removed, push the screwdriver 4.0 mm with T-handle into the socket wrench for twelve point nut and use this to apply counter-torque.
- When using a 6 mm rod, several threads of the nut will remain visible.

Option: Using the torque-limiting device

- Use the torque limiting handle to tighten the nut firmly. Insert the hexagonal socket wrench 5.0 mm with T-handle into the torque-limiting device. Tighten the nut until the torque-limiting device disengages.
- To get the hexagonal socket wrench to engage in the hexagonal socket of the stick, apply a little pressure to the socket wrench and move it back and forth.

Distraction or compression of adjacent implants

Distraction or compression with corresponding forceps

- Once the rod has been introduced and loosely attached to the implant, distraction or compression can be performed.
- Before tightening the nut on the implant, use the spreader for distraction or the compression forceps for compression.
- Option: Additional use of fixation ring:

∅ Rod	Fixation ring
5.0 mm	498.909
6.0 mm	498.910 or 498.911

- Use a fixation ring if the two implants are too far apart. Place the fixation ring on the rod using the small hexagonal screwdriver and the holding sleeve.
- Perform the distraction or compression. The implant-rod connection must be loose during this procedure.
- Remove the fixation ring and tighten the implant nut firmly.
- Option: Additional use of holding forceps for rods: The appropriate holding forceps for 5 mm or 6 mm rods may be used instead of a fixation ring. Attach forceps to rod and perform the distraction or compression operation.

Insertion of vertebral body screws with washer (anterior approach)

- The vertebral body screws for anterior approach (∅ 6.2 and 8.0 mm) have large thread flanks compared to the pedicle screws.
- Flat and angled washers can be used with anterior fixation constructs to distribute the force of the screw over the bone. The angled washers form a fixed angle with the screw.

Prepare screw hole and determine screw length

∅ Screw	∅ Probe
6.2 mm	2.8 mm (388.538)
8.0 mm	3.8 mm (388.540)

- Determine the entry point for the screw, ideally selecting it at the junction of the pedicle with the vertebral body.
- Align the pedicle awl perpendicular to the contralateral side and prepare the screw hole. Use the appropriate pedicle probe to deepen the screw hole until you have penetrated the opposite cortex.
- Use the length indicator to determine the length of the vertebral body screw. Be aware of additional screw length needed because of the washer.

Insert washer

- Insert flat washer and screw
 - Place the flat washer on the concavity of the vertebral body with the convex side down.
 - Pick up a vertebral body screw with dual opening as described in step “Implant handling using the stick”. Insert the screw in the prepared vertebral body until the screw head is well seated. Press the release button on the handle to detach the handle from the stick.

– Insert angled washer and screw

- Press the loading button on the inserter and hold it down while picking up a washer. Anchor the washer in the bone by tapping lightly on the inserter.
- Press the loading button on the inserter down and remove the inserter.
- Pick up a vertebral body screw with dual opening as described in step “Implant handling using the stick”. Insert the screw in the prepared vertebral body until the screw head is well seated. Press the release button to detach the handle from the stick.

Connecting rod and implant using rod connector

- Rod connectors are used in cases in which the distances between rod and implant cannot be bridged with the persuader. All rod connectors are open and can be applied at any point in the intervention. When using rod connectors, front-opening hooks must be used, or the pedicle screws must be rotated 90°.

Fasten rod connector to rod

- Position the rod connector on the rod and insert the ribbed part of the rod connector in the hook or the front-opening screw. Screw the set screw of the rod connector tight using the small hexagonal screwdriver.

Connect rod connector to implant

- Place the sleeve 499.302/ 499.302S and the twelve point nut on the implant. Tighten the nut firmly with the socket wrench for twelve point nut, with L-handle, and apply counter-torque using the socket wrench 5.0 mm, with T-handle, mounted on the stick.
- Use only the sleeve 499.302/ 499.302S with rod connectors.

Connecting two rods - Option A: Connecting two rods with 6 mm cross-link clamps

- Transverse connectors are designed to connect the two longitudinal rods.

Mount first cross-link clamp

- Assemble the small hexagonal screwdriver and the holding sleeve with locking catches. Retract the holding sleeve.
- To pick up the pre-assembled cross-link clamp, insert the hexagonal screwdriver in the fixing screw of the clamp, push the holding sleeve downwards and the locking catches over the sleeve of the cross-link clamp.
- Retract the holding sleeve slightly, place the clamp on the rod and let go of the holding sleeve.

Insert rod for transverse connector

- The design of the transverse connection sleeve with the two indentations on the upper side means that the transverse connector rod can be angled by up to ± 20° as necessary.
- Determine the appropriate length of the rod for transverse connector ∅ 3.5 mm. If necessary, cut the rod to size with the rod cutting and bending device.
- Hold the clamp with the small hexagonal screwdriver and pass the cross-link rod ∅ 3.5 mm through the hole in the cross-link clamp. If necessary, use the holding forceps to insert the rod for transverse connector. Tighten the set screw of the cross-link clamp firmly with the small hexagonal screwdriver.

Mount second cross-link clamp

- Repeat the procedure described in step “Mount first cross-link clamp” for the second clamp on the opposite rod.
- Pass the cross-link rod ∅ 3.5 mm through the hole in the second clamp so that it projects 5 mm above the clamp. Tighten the set screw firmly with the small hexagonal screwdriver.

Distract cross-link assembly (optional)

- Loosen one of the set screws, place the holding forceps next to the clamp and carry out the distraction with the spreader forceps.
- Retighten the set screw tightly with the small hexagonal screwdriver.

Connecting two rods - Option B: Connecting two 5 mm rods with transverse connectors

- Transverse connectors are designed to connect the two longitudinal rods.

Assemble transverse connectors

- Outside the operating field pass a cross-link rod of a suitable length through the two cross-link clamps. Either one right and one left clamp or two identical clamps can be used depending on the spatial conditions.
- Alternative: In the case of distances of less than 30 mm between the two rods to be connected, one of the two cross-link clamps must be replaced by a cross-link clamp with rod. Push the rod of the cross-link clamp with rod through the second cross-link clamp.
- Do not tighten the set screws firmly at this stage.

Mount transverse connectors on rods

- Click the assembled transverse connectors on the rods. Completely loosen the fixation screws for the rod (large screws) to do this.
- The 3.5 mm cross-link rod can be angled up to ±15°.
- If the transverse connector cannot be clicked on to the rod, loosen the fixing screws for the rod completely at both cross-link clamps.

Fix transverse connector

- First tighten the fixing screws for the rod of both cross-link clamps firmly with the hexagonal screwdriver 4.0 mm with T-handle. Then tighten both set screws of the \varnothing 3.5 mm cross-link rod firmly with the hexagonal screwdriver 2.5 mm.

Distract cross-link assembly (optional)

- Loosen one of the set screws with the small hexagonal screwdriver, place the holding forceps next to the relevant clamp and carry out the distraction with the spreader forceps. Retighten the set screws.

USS II Polyaxial Spine System

Open pedicles and determine screw lengths

- With the pedicle awl, open the cortex of the pedicles by inserting the awl until the shoulder of the awl contacts the bone. Continue opening the pedicles using the pedicle probe \varnothing 3.8 mm.
- Determine the lengths of the USS II polyaxial screws.
- If screws \varnothing 7.0 mm are implanted as the first screws, use the pedicle probe \varnothing 4.8 mm. If screws \varnothing 4.2 mm are implanted as the first screws, use the pedicle probe \varnothing 2.8 mm.

Insert screws into pedicles

- Pick up the appropriate screw from the screw rack using the screwdriver and the holding sleeve. Insert the screw into the prepared pedicle until the screw is well seated.
- If cancellous bone screws with a length of 70 mm or longer are inserted, use the screwdriver shaft 03.607.002 attached to the USS II polyaxial handle.

Prepare seat for polyaxial 3-D heads

- Apply the reamer guided by the screwdriver over the head of the screw. To ensure free movement of the polyaxial 3-D head, either ream away excessive bone or back-out the screw until the red mark is visible.
- To ream away bone, move the reamer back and forth until the red mark on the screwdriver shaft becomes visible.
- Make sure that the screwdriver is well inserted during the procedure.

Insert 3-D heads

- The technique of head insertion is the same no matter which heads (for \varnothing 5.0 mm rods or for \varnothing 6.0 mm rods) are used.
- Insert a screw holder into the appropriate 3-D head on the loading station. Make sure that the black markings (flat surface of the screw holder) point towards the rod opening of the 3-D head. Slide the positioning pliers over the screw holder and secure them by pulling down the plier handles. With the straight handle, pick up the head and place it onto the screw.
- Press the pliers to push down the locking ring over the screw head. The 3-D head is now secured but can still be rotated in all directions.

Select and insert rods

- Determine the length and curvature of the rods. The $\pm 25^\circ$ polyaxial flexibility of the screw heads equates to a lateral screw offset up to ± 5.1 mm. If necessary, bend the rods using the bending pliers.
- In multilevel cases, bend the rod according to the curvature of the rod template determined in step "Insert 3-D heads".
- Insert the rods with the holding forceps into the side-opening, polyaxial screw heads. The heads can be manipulated and aligned using the screw holder with the handle.
- If screw holders have to be removed and re-inserted during surgery, the positioner for screw holder can be used. If the rod is not inserted yet, apply the positioner with the slender end over the top of the 3-D head. If rod, sleeve and nut are already inserted, apply the positioner with the wider end over the 3-D head.

Optional: Align rod and screw head with rod introduction pliers

- If necessary, use the rod introduction pliers to align the rod with a screw head.
- Following alignment, use the sleeve pusher to insert sleeves.
- Once the sleeve has been inserted with the sleeve pusher, the nut can be inserted with the socket wrench prior to final tightening (step "Tighten the nuts").

Insert sleeves and nuts

- Use the self-holding socket wrench to pick up a sleeve and nut from the loading station. Slide them over the screw holder onto the screw head and tighten the nut slightly. Although the rods are now secured in the side-opening of the screw, the 3-D heads still remain mobile.
- For constructions with more than two screws on each side, start with the screw heads in the center.

Tighten the nuts

- Use the socket wrench with L-handle to final tighten the nuts. Counteract torque using the socket wrench with T-handle placed over the screw holder.
- It is necessary to apply a tightening moment of 12 Nm to secure the polyaxial screw heads tightly. To achieve this, the torque-limiting handle 12 Nm may be used instead of the socket wrench.
- Remove the screw holders when all the screws are finally tightened.

USS II Ilio-Sacral Spine System

Iliac fixation with iliac connector

Extend construct caudally to include S1

- Instrument the spine with a rod construct down to S1 according to the surgical procedure of the Universal Spine System (USS) implants used (e.g., USS II polyaxial). In S1, it is recommended to use an USS II polyaxial cancellous bone screw.
- Leave at least 3 cm excess rod caudally to the S1 screw for later placement of the iliac connector.
- Alternative: Instead of applying the iliac connectors to the rod as the last step in the surgery, it is also possible to insert all screws and iliac connectors first, and then apply the rod.

Determine size of iliac connector

- Use the templates to determine the proper implant size. Either the telescopic or the fixed length iliac connector may be used.
- Fixed length connector: The distances indicated on the template correspond to the implant size (mm).
- Telescopic connector: The distance varies between 17 and 27 mm.

Attach clamp

- Pick up the corresponding clamp for the telescopic or fixed-length connector from the tray using the clamp holder.
- The clamp holder is approximately twice as long as the USS II polyaxial screw holder.
- Attach the clamp to the rod from the midline. If necessary, remove excessive bone below the rod to create enough space for the clamp.

Place iliac connector and create screw entry point

- Place the iliac connector over the clamp holder. With the implant in place, verify that the correct implant size has been chosen.
- Use a pedicle probe to drill the screw hole in the center of the opening of the iliac connector. This ensures that the screw will be placed at the correct distance to the rod.
- After drilling the screw hole, remove the iliac connector.
- Alternative screw placement in the ilium: The screw may be placed from the inner side of the iliac crest in order to reduce the extent of soft tissue exposure.

Insert bone screw

- Pick up the appropriate screw from the screw rack using the screwdriver and the holding sleeve. Insert the screw into the prepared ilium until the screw is well seated.
- For cancellous bone screws with a length of 70 mm or longer, use the screwdriver shaft attached to the USS II polyaxial handle.

Expose screw head

- Place the reamer guided by the screwdriver over the screw head. Ream away excessive bone by moving the reamer back and forth until the red mark on the screwdriver shaft becomes visible.
- If more bone that may block the connector has to be removed, use a chisel or gauge pliers.

Click on the collet

- Use the USS II polyaxial screw holder to pick up a collet from the tray. Optionally, attach the handle.
- Click on the collet and orient the notch on the collet in direction of the screw angulation to achieve larger angles. Afterwards release the handle leaving the screw holder attached to the collet.

Insert iliac connector

- Attach the clamp to the rod from the midline.
- Slide the iliac connector over both the clamp holder and the screw holder.

Lock iliac connector

- Pick up a nut using the socket wrench with straight handle (black), place it over the collet of the iliac screw and tighten it slightly.
- Always first place a nut on the collet (iliac screw) and then one on the clamp (rod).
- Pre-tighten the nut on the iliac screw at least two revolutions. This is how the iliac connector is firmly attached to the bone screw while the polyaxiality is still maintained. Pull on the screw holder to check if the collet has been attached correctly.
- Secondly, apply a nut on the clamp, and tighten it slightly.
- For final tightening, change the socket wrench with black handle to the one with L-handle. Use the socket wrench with T-handle as counter torque.
- Optional: Lock the clamp of the connector with the spreader forceps
- 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

Extend construct caudally to include S1

- Place the pedicle screws according to the surgical procedure of the USS implant system used (e.g., USS II polyaxial).

Prepare hole for the S2 pedicle screw

- Open the pedicle using a pedicle probe.

Insert S2 screw

- Pick up the appropriate screw from the screw rack using the screwdriver and the holding sleeve. Insert the screw into the prepared pedicle until the screw is well seated. Ideally, the screw is placed bicortically.

Expose screw head

- Place the reamer guided by the screwdriver over the screw head. Ream away excessive bone by moving the reamer back and forth until the red mark on the screwdriver shaft becomes visible.

Click on the collet

- Use the USS II polyaxial screw holder to pick up a collet from the tray. Optionally, attach the handle.
- Click on the collet and orient the notch on the collet in direction of the screw angulation to achieve larger angles. Afterwards release the handle leaving the screw holder attached to the collet.
- Alternatively, an USS II polyaxial 3-D head may be clicked on the screw instead of using the S2 connector.

Insertion S2 connector left/right

- Insert S2 connector (left or right)
 - Slide the connector over the screw holder onto the collet.
 - Pick up a nut using the socket wrench with L-handle and place it over the collet of the S2 screw.
 - Pre-tighten the nut on the S2 screw at least two revolutions. This is how the S2 connector is firmly attached to the bone screw while the polyaxiality is still maintained. Check for a secure seat by pulling on the screw holder.
- Insert rod and lock nuts
 - Insert the rod into the connector.
 - Connect the rod to the remaining screws according to the surgical procedure of the USS implant system used (e.g., USS II polyaxial).
 - Use the screwdriver to lock the set screw on the S2 connector.
 - Use the socket wrench with T-handle as countertorque for final tightening.

Insertion S2 connector for rod end

- Insert connector for rod end
 - Insert contoured rod into the connector and lock the set screw with the 2.5 mm screwdriver. Slide the connector over the screw holder onto the collet.
 - Pick up a nut using the socket wrench with L-handle and place it over the collet of the S2 screw.
 - Pre-tighten the nut on the S2 screw at least two revolutions. This is how the S2 connector is firmly attached to the bone screw while the polyaxiality is still maintained. Check for a secure seat by pulling on the screw holder.
- Connect rod to remaining screws and lock nuts
 - Connect the rod to the remaining screws according to the surgical procedure of the USS implant system used (e.g., USS II polyaxial).
 - Use the socket wrench with T-handle as countertorque for final tightening.

USS II Polyaxial Perforated

Preoperative planning

- Preoperative planning includes evaluation and assessment of the patient with regard to the specifications of the bone cement used for augmenting USS II polyaxial perforated screws (see VERTECEM V+ System Instructions for Use).
- Proper imaging equipment must be used to determine correct implant dimensions in relation to the anatomy.
- The decision whether or not to augment USS II polyaxial perforated screws can be taken intraoperatively, based on tactile feedback upon pedicle preparation and screw insertion. If screws are augmented, bilateral screw augmentation is recommended.

Approach

- This step contains supplementary instructions on handling USS II Polyaxial Perforated pedicle screws. For handling standard USS II Polyaxial pedicle screws, please refer to surgical procedural steps of "USS II Polyaxial Spine System".

Open pedicles and determine screw lengths

- With the pedicle awl, open the cortex of the pedicles to a depth of 10 mm. Continue opening the pedicles using the pedicle probe \varnothing 3.8 mm.
- Determine the lengths of the USS II polyaxial screws.
- If screws \varnothing 7.0 mm are implanted as the first screws, use the pedicle probe \varnothing 4.8 mm.
- Sufficient preparation of the screw channel is essential to ensure optimal cement cloud formation.

Insert screws into pedicles

- Pick up the appropriate screw from the screw rack using the screwdriver and the holding sleeve. Insert the screw into the prepared pedicle until the screw is well seated.

Assess proper screw placement

- Assess the cortical shell for perforations.
- Confirm appropriate screw lengths. Choose screws with the maximum possible diameter and length to achieve desired stability.

Prepare seat for 3-D heads

- Apply the reamer guided by the screwdriver over the head of the screw. To ensure free movement of the polyaxial 3-D head, either ream away excessive bone or back-out the screw until the red mark is visible.
- To ream away bone, move the reamer back and forth until the red mark on the screwdriver shaft becomes visible.

Preparing the augmentation channel

- Use the cleaning stylet, clear the cannula for proper cement injection. Visualize the stylet position under image intensifier.
- Optionally, a Kirschner wire of \varnothing 2.0 mm can be used.

Cement Handling

- Cement handling with VERTECEM V+.

Prepare cement

- For handling VERTECEM V+ Cement, please refer to the VERTECEM V+ Instructions for Use.

Injection sequence

- Option a: Simple adapter for perforated pedicle screws
 - Attach simple adapter onto the syringes.
 - Connect the syringe to the screw.
- Option b: Needle adapter kit with Luer-lock
 - Connect the needle adapter to the screws.
 - Additionally, the cement in the adapter can be utilized using the corresponding plunger.
- As soon as the cement is ready, connect the syringes with respective adapters (see option a and b) to the pedicle screws to be augmented.
- Inject as much cement as required until it slowly starts to extrude from the perforations.
- Continue to add cement to each screw using continuous image intensifier control. A growing cloud pattern should form. If a spider web-like pattern forms, wait approximately 30 to 45 seconds or proceed with another screw and return to the present screw later.
- If more cement is needed or the injection pressure is too high, switch to the 1 ml syringes. Start again with the first screw.
- After injection is made using the locking needle adapter or the needle adapter, the cleaning stylet should be used to create a cement backflow recess. Remove the syringe or plunger from the adapter and insert the cleaning stylet. Use image intensifier to confirm that the tip of the cleaning stylet protrudes through the tip of the adapter.

Attach construct

- Continue with "Prepare seat for 3-D heads", selecting and inserting rods, inserting sleeves, nuts and final nut tightening from the surgical procedural steps of "USS II Polyaxial Spine System".

Kirschner wire screw placement

Open pedicle

- Select the cannulated pedicle awl that corresponds to the screw diameter. Fit the 1.6 mm trocar and trocar holder together and screw fully into the pedicle awl. Open the pedicle as defined in surgical procedural steps of "USS II Polyaxial".
- Unscrew and remove the trocar holder with the trocar from the pedicle awl. The awl remains in the pedicle.
- Insert a 1.6 mm Kirschner wire through the awl in the pedicle and vertebral body. If necessary, use the tamp.
- Check the depth of penetration and carefully remove the awl.
- The red marking on the tamp represents a penetration depth of the Kirschner wire tip of approx. 35 mm.

Prepare screw channel

- Carefully guide the cannulated pedicle probe over the Kirschner wire in the opened pedicle and prepare the screw channel along the guide wire. Further instructions regarding screw channel preparation can be found in surgical procedural steps of "USS II Polyaxial Spine System".

Tap the thread (optional)

- If necessary, prepare the pedicle with the appropriate tap. The tap must correspond to the screw type and diameter.
- Fit the protection sleeve onto the cannulated tap and ensure that the cutting surfaces are fully covered (arrows must point towards each other).
- Carefully guide the tap over the Kirschner wire into the recessed pedicle. Tap the thread along the guide wire.

Screw in the screw

- Select the holding sleeve according to the screw type.
- Pick up the screw using the holding sleeve and carefully insert over Kirschner wire.
- Screw in the pedicle screw until the tip of the screw is beyond the posterior wall of the vertebral body and remove the guide wire in order to avoid its uncontrolled further advancing. Ensure that there is enough space to allow the 3-D head to move freely.
- The further steps are described in surgical procedural steps of “USS II Polyaxial Spine System”.

USS Low Profile Spine System

Handling implants with the stick

Attaching handle to stick

- Press the button on top of the USS universal handle and simultaneously insert the stick from below into the handle.

Picking up of implants

- Insert the tip of the stick into the head of the implant. Tighten the stick to the implant by rotating the knurled knob of the USS universal handle.

Release of stick

- After implant insertion, simultaneously press the button and remove the handle to release the stick.

Insert pedicle screws

Open pedicle

- Use the awl that corresponds to the selected screw diameter and perforate the cortex of the pedicle.
- Continue opening the pedicle canal using one of the USS pedicle probes.

Probe pedicle channel

- Palpate the inner walls of the pedicle screw channel using the straight or curved feeler in order to check the wall for perforations.

Insert pedicle screw into pedicle

- Determine the length of the pedicle screws using the length indicator. Confirm the position and orientation with image intensifier control. Pick up the appropriate pedicle screw from the tray as described in “Handling implants with the stick”.
- Insert the screw into the prepared pedicle until the screw head is well seated, i.e., the side opening of the implant head should point in the desired direction and the horizontal position should be aligned with the rod trajectory. In order to disconnect the handle from the stick, press the release button.
- If a rod connector is used, the opening of the screw must be oriented perpendicular to the rod trajectory.

Pedicle hook positioning

- The USS low profile pedicle hooks can be anchored in the pedicle with a single \varnothing 3.2 mm USS screw for pedicle hook.

Prepare seat for pedicle hook

- Prepare the pedicle using the USS pedicle feeler. Place the pedicle feeler between the inferior and superior facet joints.
- To facilitate insertion of the pedicle hook, remove a small portion of the inferior facet with an osteotome. The pedicle feeler has marks. When the last mark in direction of the tip is reached, sufficient bone has been removed to accommodate the hook around the pedicle.
- Check the position of the pedicle feeler by moving it laterally and cranially. The feeler should not move.
- Remove the pedicle feeler.

Position pedicle hook

- Pick up a pedicle hook from the tray with the stick as described in “Handling implants with the stick”.
- Use a front opening hook if a rod connector is mounted on the hook.
- Insert the hook positioner into the screw hole of the pedicle hook and move the hook into the previously prepared seat. Check that the pedicle hook is snug around the pedicle by axial loading of the hook positioner and also by pushing laterally. The pedicle hook should not move.
- Gently tap the hook positioner with a hammer to firmly seat the hook. Remove the hook positioner and the handle. The stick remains attached to the hook.

Drill hole for screw \varnothing 3.2 mm

- Drill the screw hole with the three-fluted drill bit together with the USS drill sleeve. The two components of the drill sleeve (sleeve and handle) must be screwed together before use.

Determine screw length

- Remove the drill sleeve and determine the depth with the depth gauge.

Insert screw \varnothing 3.2 mm

- Select a suitable length USS screw for pedicle hook and insert it into the previously prepared drill hole using the hexagonal screwdriver and the holding sleeve.
- The pedicle hook is now attached to the pedicle.

Lamina hook positioning

Prepare seat for lamina hook

- The lamina hook can be placed around the superior or inferior portion of the lamina. Carefully remove the ligamentum flavum with a rongeur to ensure a snug fit of the hook on the lamina. Remove a small portion of the lamina with a bone rongeur. Check the seat for the lamina hook using the USS lamina feeler.
- Remove the lamina feeler.

Position lamina hook

- Pick up an appropriate lamina hook from the tray with the stick as described in “Handling implants with the stick”.
- The inferior part of the lamina hook must fit snugly with the lamina.
- Use a front opening hook if a rod connector is mounted on the hook.
- Insert the hook positioner into the positioning hole of the hook and move the lamina hook into the previously prepared seat.
- Remove the hook positioner. The stick remains attached to the hook until the hook is connected to the rod.

Angled lamina hook positioning at the transverse process

Prepare seat for angled lamina hook

- Remove the soft tissue from the transverse process. Place the USS lamina feeler around the transverse process in order to elevate the soft tissue attachments from the anterior portion of the transverse process.
- Remove the lamina feeler.

Position angled lamina hook

- Pick up an appropriate angled lamina hook from the tray with the stick as described in “Handling implants with the stick”.
- Use a front-opening hook if a rod connector is mounted on the hook.
- Insert the hook positioner into the positioning hole of the hook and ease the angled lamina hook into the previously prepared seat. Remove the hook positioner. The stick remains attached to the hook until the hook is connected to the rod.

Rod contouring

- Use a trial rod to determine the shape and length of the rod to be inserted. Contour the rod using either the bending pliers with rolls or the USS bending irons.

Tightening of construct

Pick up and place sleeve with the universal handle

- The sleeve and nut are picked up with the universal handle from the tray. Make sure that the upper side of the nut is correctly oriented; i.e., the crank of the nut faces downward and fits the sleeve correctly. Release the sleeve and nut from the stick by pushing on the release button.

Loosely tighten the nut

- Use the straight socket wrench to loosely tighten the nut. The screw to rod connection is now loosely fixed and allows for further manipulations along the construct.

Firmly tighten the nut

- Use the counter torque instrument with L-handle, which acts directly on the rod. The socket wrench with L-handle is used to tighten the nuts.

Options:

- Use the straight socket wrench to tighten the nut and provide counter torque with the USS LP counter torque instrument with L-handle.
- Use the socket wrench 11 mm with L-handle to firmly tighten the nut while providing counter torque with the USS socket wrench 6 mm applied on the stick.

Introduction of rods into side openings

Using the rod introduction pliers (persuader)

- The persuader is used in situations when the distance between implant and rod is significant. The persuader permits introduction of the 6 mm rod into the side opening of the implant.
- The persuader is also used when applying the segmental derotation technique for scoliosis correction.

Option: Alternative method without persuader

- If the rod is aligned horizontally to the side opening, the rod crimping pliers can be used to push the rod into the implant opening.

Mount sleeve pusher onto persuader

- Place the USS sleeve pusher onto the cylinder of the persuader. The handle of the sleeve pusher must be located on the side of the persuader with the arrow pointing to the outer side. Pick up a sleeve from the tray.

Locate persuader on implants

- Slide the cylinder of the persuader over the stick and orient the leg of the pliers towards the rod. Engage the rod with the opposite jaw of the persuader and lightly squeeze the handle to push the rod towards the implant.

Attach support for rod introduction pliers

- The support serves as a locking device when lifting the implant towards the rod.
- Slide the support over the protruding end of the stick in the configuration with the persuader mounted over the stick. The forked opening of the support must face upwards. The lever must be pulled and then released so that the fork of the support engages in the hexagon of the stick.

Bring rod towards side opening of implant

- Place the spreader forceps on the stick between the distraction clip and the persuader. Slowly open the spreader to bring the implant up towards the rod. When the opening is opposite to the rod, close the persuader to fully engage the rod.

Place sleeve over implant and rod

- Push the sleeve pusher down the cylinder to place the sleeve over the rod and implant. When retracting the sleeve pusher, it is important to leave the sleeve on the implant and rod.
- If the sleeve cannot be readily placed in position:
 - Either try to align the screw to the rod by slightly turning the stick using the USS socket wrench 6 mm
 - Or gently tap the sleeve pusher to position the sleeve on the implant using the USS low profile hook positioner by placing it in the round dent on the handle of the sleeve pusher.

Attach implant to rod

- Remove the persuader. The implant is now loosely fixed by the sleeve. In order to secure the assembly, add a nut over the implant and tighten it as described in step "Tightening of construct".

Distraction or compression of adjacent implants

Distraction or compression

- Once the rod has been introduced and attached to the implants, distraction or compression can be carried out. This is usually performed with two neighbouring implants with one implant firmly tightened and the other loose. Distraction is carried out with the spreader forceps and compression with the compression forceps. The tip of the instrument is placed on the sleeve of the implants.

Options:

- Use one of the following alternative methods when forceps cannot be applied directly to the implants because the neighbouring implants are too far apart.
 - Additional use of holding forceps for rods: Instead of using the fixation ring, secure the holding forceps next to the dedicated implant and carry out distraction or compression.
 - Additional use of fixation ring: A fixation ring is placed adjacent to the implant where compression or distraction is to be performed. The ring is placed onto the rod using the hexagonal screwdriver and the holding sleeve. The distraction or compression is now carried out over the implant and the fixation ring. The implant must be loose (i.e., not rigidly fixed to the rod) during this procedure. Remove the fixation ring after tightening the nut of the implant.

Connecting a rod to an implant with a rod connector

- Rod connectors allow the bridging of lateral distances in cases where the rod is offset from the implant. The rod connector can be attached to the rod at any point during the surgery. To accommodate the rod connector, the side opening of the pedicle screws is to be oriented perpendicular to the rod whereas the front-opening models are to be selected for the hooks.

Fasten rod connector to rod

- Position the rod connector on the rod and insert the ribbed part of the rod connector in the side opening of the implant. Tighten the set screw of the rod connector using the small hexagonal screwdriver.

Connect rod connector to implant

- Add a sleeve and nut over the implant and secure the assembly as described in step "Tightening of construct".

USS Small Stature/Paediatric Spine System

Implant handling using the stick

- The dual-opening pedicle screws have the same head as the pedicle, lamina and angled hooks. The following handling instructions hence refer to both the pedicle screws and all three hook types (referred to as "implants" in surgical procedural steps of "USS Small Stature/Paediatric Spine System").

Attach handle to stick

- Press the knurled release button on the upper end of the handle, and simultaneously attach the hook and screw holder with hexagonal 4.0 mm (also termed the "stick") to the handle.

Pick up implant

- Pick up the dual-opening implant with the stick and handle by rotating the release button on the handle.

Release handle from stick

- Insert the implant. To release the handle from the stick, press the release button on the handle.

Insert pedicle screws (posterior approach)

Open pedicle and determine screw length

- Use one of the pedicle awls to open the cortex of the pedicle to a depth of 10 mm. Continue opening the pedicle using one of the pedicle probes with markings at 30, 40 and 50 mm.
 - 388.538 for \varnothing 4.2 mm screws;
 - 388.540 for \varnothing 5.0 and 6.0 mm screws;
 - 388.539 for \varnothing 7.0 mm screws.
- Determine the length of the pedicle screws with the depth gauge for pedicle screws.

Probe pedicle channel

- Using the straight feeler or the curved feeler, probe the pedicle screw channel in order to check for perforations in the walls.

Insert pedicle screw into pedicle

- Pick up the pedicle screw as described in "Handling implants with the stick".
- Insert the pedicle screw into the prepared pedicle until the screw head is well seated and one of the openings points towards the rod that is to be subsequently inserted. To disconnect the stick from the handle, press the release button on the handle.
- If using a rod connector, align the screw head such that one of the openings is perpendicular to the rod.

Insert pedicle screws with washers (only for anterior approach)

- Flat and angled washers can be used with anterior fixation constructs to distribute the force of the screw over the bone. The angled washers form a fixed angle with the screw.

Prepare screw hole and determine screw length

- Determine the entry point for the screw, preferably at the junction of the pedicle and the vertebral body.
- Align the pedicle awl perpendicular to the contralateral side and prepare the screw hole. Enlarge the screw hole using the pedicle probe until it penetrates the contralateral cortex.
- Determine the length of the pedicle screw using the depth gauge for pedicle screw.

Insert flat washer and screw

- Place a flat washer with the convex side facing down onto the concavity of the vertebral body.
- Pick up a dual-opening pedicle screw as described in "Handling implants with the stick". Insert the pedicle screw into the prepared vertebral body until the screw head is well seated. To release the stick from the handle, press the release button on the handle.

Insert angled washer and screw

- While pressing the release button, load an angled washer in the inserter. Anchor the washer in the bone by gently tapping the inserter.
- Once the washer is firmly seated, remove the inserter by pressing the release button. Pick up a dual-opening pedicle screw as described in "Insert pedicle screws (Posterior approach)". Insert the pedicle screw into the prepared vertebral body until the screw head is well seated. To disconnect the stick from the handle, press the release button on the handle.

Position pedicle hook

- The USS small stature/paediatric pedicle hooks can be anchored in the pedicle with a single \varnothing 3.2 mm USS screw for pedicle hook.

Prepare seat for pedicle hook

- Prepare the pedicle using the pedicle feeler. Place the pedicle feeler between the inferior and superior facet joints.
- To facilitate the insertion of the pedicle hook, remove a small portion of the inferior facet with an osteotome. The pedicle feeler has marks. When the last mark in direction of the tip is reached, sufficient bone has been removed to accommodate the hook around the pedicle.
- Check the optimal position of the pedicle feeler by moving it laterally and cranially.
- Remove the pedicle feeler.

Position pedicle hook

- Using the stick, pick up a pedicle hook from the set, as described in “Insert pedicle screws (Posterior approach)”.
- Use a front-opening hook if a rod connector is needed.
- Insert the hook positioner into the positioning hole of the hook and ease the pedicle hook into the previously prepared seat. Ensure that the pedicle hook is snug around the pedicle by pushing the hook positioner axially and laterally. The pedicle hook should not move. Gently tap the hook positioner with a hammer to firmly seat the hook.
- Remove the hook positioner and the handle. The stick remains attached to the hook.

Drill hole for screw \varnothing 3.2 mm

- To anchor the pedicle hook to the pedicle, a screw \varnothing 3.2 mm can be inserted through the hole at the back of the hook.
- Use a three-fluted drill bit \varnothing 2.0 mm together with the USS drill sleeve 2.0 and an oscillating drill to drill the screw hole. The drill sleeve consists of two components, the drill sleeve and the handle. These two components must be screwed together before use.

Determine screw length

- Remove the drill sleeve and determine the depth with the depth gauge.

Insert \varnothing 3.2 mm screw

- Pick up an appropriate length USS screw for pedicle hook using the holding sleeve and the hexagonal screwdriver and insert the screw into the previously prepared drill hole. The pedicle hook is now attached to the pedicle.

Position lamina hook

Prepare seat for lamina hook

- The lamina hook can be placed around either the superior or inferior portion of the lamina. Prepare the seat for the lamina hook using the lamina feeler. To ensure good seating of the hook, carefully remove the ligamentum flavum and a small portion of the lamina with a rongeur.
- Remove the lamina feeler.

Position lamina hook

- Using the stick, pick up an appropriate lamina hook from the set, as described in “Handling implants with the stick”.
- Use a front-opening hook if a rod connector is needed.
- Insert the hook positioner into the positioning hole of the hook and ease the lamina hook into the previously prepared seat. The inferior part of the lamina hook must fit snugly with the lamina.
- Remove the hook positioner and the handle. The stick remains attached to the hook.

Angled lamina hook positioning

Prepare seat for angled lamina hook

- Remove the soft tissue from the transverse process. Place the lamina feeler around the transverse process, elevating the soft tissue attachments from the anterior portion of the transverse process.
- Remove the lamina feeler.

Angled lamina hook positioning

- Using the stick, pick up an appropriate angled lamina hook from the set, as described in “Handling implants with the stick”.
- Use a front-opening hook if a rod connector is needed.
- Insert the hook positioner into the positioning hole of the hook and ease the angled lamina hook into the previously prepared seat.
- Remove the hook positioner and the handle. The stick remains attached to the hook.

Rod contouring

- Use the bending template \varnothing 5.0 mm to determine the proper rod contour and length.
- Contour the rod using either the bending pliers with rolls for rods \varnothing 5.0 mm, with bending radius adjustment, or the bending irons.
- Hook/screw offset: Anatomical conditions sometimes result in the implants not being aligned in a straight line. The screws and hooks have a 7.6 mm offset and the dual opening allows for insertion of the rod to either side of the pedicle screws and hooks.

Locking implants to rods

- The rod \varnothing 5.0 mm is secured with a sleeve and nut.

Pick up and locate sleeve with sleeve positioner

- Fit the sleeve pusher to the sleeve positioner. Pick up a sleeve, ensuring that the shorter leg of the sleeve pusher stands above the narrow fluted side of the sleeve. Slide the sleeve positioner over the stick and place it on the implant.
- Press down on the sleeve pusher to place the sleeve on the implant/rod. Retract the sleeve pusher. The sleeve remains on the implant/rod.

Place nut on implant

- Pick up the nut from the loading station using the socket wrench for 12-point nut, with L-handle.

- Introduce the socket wrench 5.0 mm with T-handle into the socket wrench for 12-point nut and slide together over the stick. The socket wrench 5.0 mm must engage in the hexagon of the stick, which is used to apply counter-torque.
- If the stick has already been removed, insert the screwdriver 4.0 mm with T-Handle into the socket wrench for 12-point nut and apply counter-torque.

Tighten nut

- Tighten the nut with the socket wrench for 12-point nut with L-handle. The instruments used for applying counter-torque are spring-loaded and can be kept under constant pressure by means of the T-handle. To tighten the nut further, lift off the L-handle and place it on again.

Introducing rods into dual-opening implants

- Using the USS small stature/paediatric rod introduction pliers (the persuader).
- Occasionally, a rod cannot easily be introduced into a dual-opening implant because of the distance between the rod and the implant. When using the rod introduction pliers (the persuader), the dual-opening implant can be lifted and pulled towards the rod.

Mount sleeve pusher onto persuader

- Place the sleeve pusher onto the cylinder of the persuader. Pick up a sleeve from the loading station using the sleeve pusher. The handle of the sleeve pusher must be located on the side of the persuader with the arrow.

Place persuader on implants

- Slide the cylinder of the persuader on the stick and the leg of the pliers on the rod.

Attach support for rod introduction pliers

- Slide the support for rod introduction pliers over the protruding end of the stick, and simultaneously pull the lever. The forked opening of the support must face upwards (marked TOP). Release the lever so that the support engages in the hexagon of the stick. The support for rod introduction pliers serves as a locking device when lifting the implants and allows the implants to be rotated.

Bring rod towards dual-opening implant

- Place the spreader forceps on the stick between the support and the persuader. Slowly open the spreader to bring the implant up towards the rod. When the opening of the implant is at the height of the rod, close the persuader to engage the rod.
- Remove the support for rod introduction pliers.

Place sleeve over implant and rod

- Push the sleeve pusher down the cylinder to place the sleeve over the rod and implant. Retract the sleeve pusher. The sleeve remains on the implant/rod.
- If the sleeve cannot be readily placed in position, tap the sleeve pusher gently to position the sleeve on the implant.

Attach implant to rod

- Remove the persuader. Pick up a nut using the socket wrench for 12-point nut (as described in “Locking implants to rods”), place it over the stick and screw it loosely onto the implant.

Distraction or compression of adjacent implants

Distraction or compression with corresponding forceps

- Once the rod has been introduced and loosely attached to the implant, distraction or compression can be performed.
- Before tightening the nut of the implant, use the spreader forceps for distraction, or the compression forceps for compression.
- Option: Additional use of fixation ring:
 - If the two implants are placed too far from each other, use the fixation ring for rods \varnothing 5.0 mm. Place the small hexagonal screwdriver with the holding sleeve onto the fixation ring and place it next to the implant. Carry out distraction or compression. The implant-rod connection must be loose during this procedure.
 - Remove the fixation ring and tighten the nut of the implant.

Option: Additional use of holding forceps for rods:

- Instead of using the fixation ring, secure the holding forceps for rods next to an implant and carry out the distraction or compression.

Connecting a rod to an implant with rod connectors

- Rod connectors can be used to bridge distances between rod and implant in cases where this cannot be achieved with the persuader. All USS small stature/paediatric rod connectors are open and can be applied at any point during the operation. When using rod connectors, front-opening hooks must be used, or the pedicle screws must be rotated 90°.

Fasten rod connector to rod

- Position the rod connector on the rod and insert the ribbed part of the rod connector in the hook or the front-opening screw. Tighten the set screw of the rod connector using the small hexagonal screwdriver.

Connect rod connector to implant

- Place the toothed sleeve and the 12-point nut onto the implant and tighten the nut using the socket wrench for 12-point nut with L-handle, applying counter-torque using the socket wrench 5.0 mm with T-handle mounted on the stick.
- Only use the toothed sleeve with rod connectors.

Connecting two rods with cross-link connectors

- Cross-link connectors are designed to connect the two longitudinal rods.

Assemble cross-link connectors

- Outside the operating field, push the appropriate length of cross-link rod \varnothing 3.5 mm through the two cross-link clamps. One right and one left clamp or two identical clamps can be used depending on the space available in each case.
- Alternative: If the distance between the two rods to be connected is less than 30 mm, one of the two cross-link clamps must be replaced by a cross-link clamp with rod. Push the rod of the cross-link clamp with rod through the second cross-link clamp. Do not tighten the set screws.

Mount cross-link connector

- Click the assembled cross-link connector onto the rods \varnothing 5.0 mm, ensuring that the set screws are completely unscrewed.
- The cross-link rod \varnothing 3.5 mm can be angled up to $\pm 15^\circ$.

Secure cross-link connector

- First, tighten the set screws for the rods \varnothing 5.0 mm on both cross-link clamps using the screwdriver \varnothing 4.0 mm with T-handle. Next, tighten both set screws for the cross-link rod \varnothing 3.5 mm using the hexagonal screwdriver 2.5 mm.

Distraction cross-link assembly (optional)

- Loosen one of the set screws with the small hexagonal screwdriver and perform distraction with the spreader forceps. Retighten the set screws.

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.

Implant Card & Patient Information Leaflet

If supplied with the original packaging, provide the implant card as well as the relevant information according to the patient information leaflet to the patient. The electronic file containing the patient information can be found at the following link: ic.jnjmedicaldevices.com

CE
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