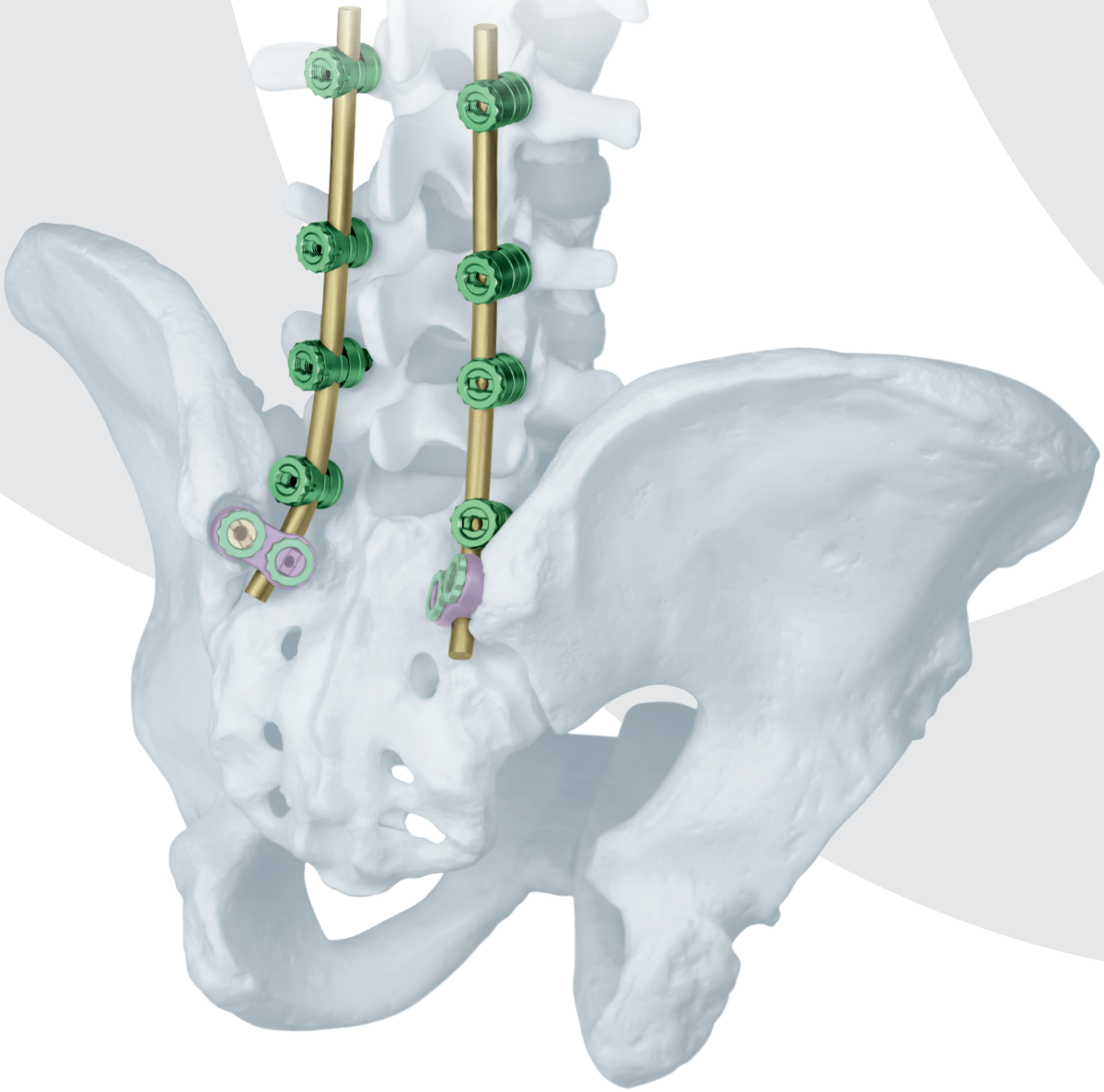
Polyaxial Screws for the Thoracolumbar Spine

USS™ II Polyaxial Spine System

Surgical Technique



DePuy Synthes

PART OF THE Johnson&Johnson FAMILY OF COMPANIES

Image intensifier control

This description alone does not provide sufficient background for direct use of DePuy Synthes products. Instruction by a surgeon experienced in handling these products is highly recommended.

Processing, Reprocessing, Care and Maintenance
For general guidelines, function control and dismantling of multi-part instruments, as well as processing guidelines for implants, please contact your local sales representative or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance
For general information about reprocessing, care and maintenance of Synthes reusable devices, instrument trays and cases, as well as processing of Synthes non-sterile implants, please consult the Important Information leaflet (SE_023827) or refer to:
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

Table of Contents

Introduction	USS™ II Polyaxial Spine System	2
	AO Spine Principles	3
Surgical Technique	Open pedicles and determine screw lengths	4
	Insert screws into pedicles	5
	Prepare seat for Polyaxial 3-D heads	6
	Insert 3-D heads	7
	Select and insert rods	8
	Insert sleeves and nuts	10
	Tighten the nuts	11
	Remobilization and/or removal	12
Indications and Contraindications		14
Bibliography		15

*For product catalog contact your local DePuy Synthes representative.

USS™ II Polyaxial Spine System

Overview

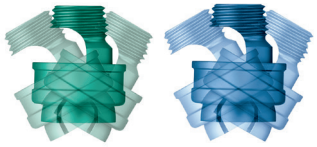
USS™ II Polyaxial Spine System combined with USS II Ilio-Sacral Spine System is designed for fixation of the thoracolumbar spine and the pelvis.

USS II nut

Sleeve

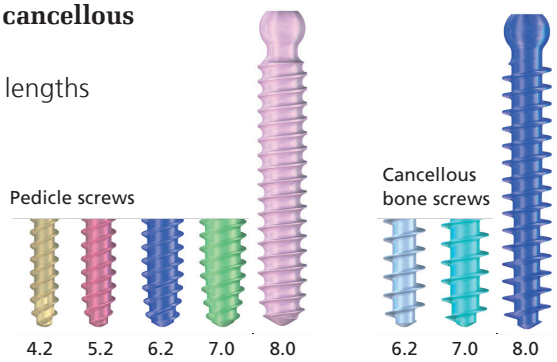
Polyaxial 3-D head

- Click-on head
- Side opening for 5 mm or 6 mm rods
- 25° deflection



Dual-core pedicle and cancellous bone screws

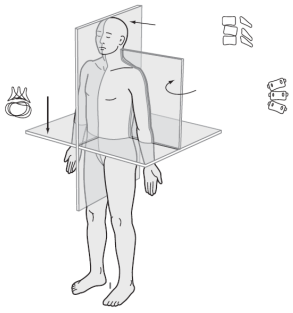
- Various diameters and lengths



AO Spine Principles

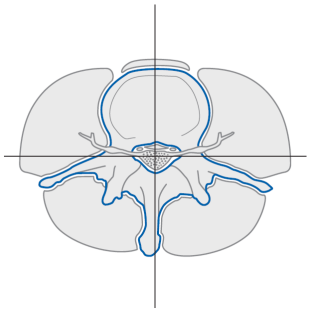
The four principles to be considered as the foundation for proper spine patient management underpin the design and delivery of the Curriculum: Stability – Alignment – Biology – Function.[1,2]

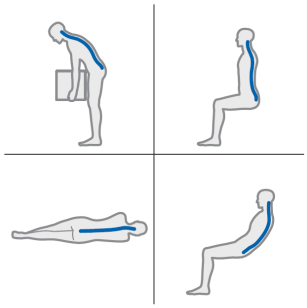
Stability
Stabilization to achieve a specific therapeutic outcome



Alignment
Balancing the spine in three dimensions

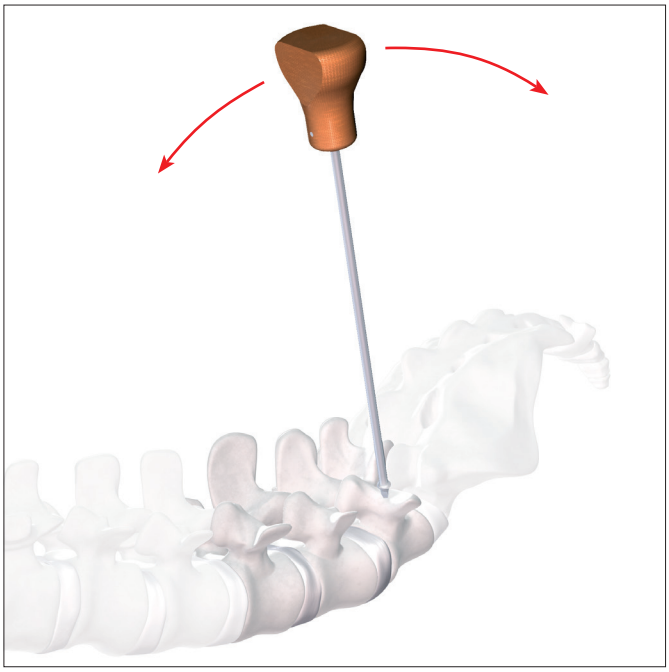
Biology
Etiology, pathogenesis, neural protection, and tissue healing





Function
Preservations and restoration of function to prevent disability

1. Open pedicles and determine screw lengths



Required instruments

388.550	Pedicle Awl Ø 4.0 mm with Canevasit Handle, length 230 mm, for Pedicle Screws Ø 5.0 to 7.0 mm
388.540	Pedicle Probe Ø 3.8 mm with Canevasit Handle, length 230 mm, for Pedicle Screws Ø 5.0 to 7.0 mm

Optional instruments

388.539	Pedicle Probe Ø 4.8 mm with Canevasit Handle, length 230 mm, for Pedicle Screws Ø 8.0 and 9.0 mm
388.538	Pedicle Probe Ø 2.8 mm, length 230 mm
388.551	Pedicle Awl Ø 3.0 mm, length 230 mm, for Screws Ø 4.0 mm and 4.2 mm

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 Ø 3.8 mm.

Determine the lengths of the USS II Polyaxial screws.

Note: **If screws Ø 7.0 mm are implanted as the first screws, use the Pedicle Probe Ø 4.8 mm. If screws Ø 4.2 mm are implanted as the first screws, use the Pedicle Probe Ø 2.8 mm.**

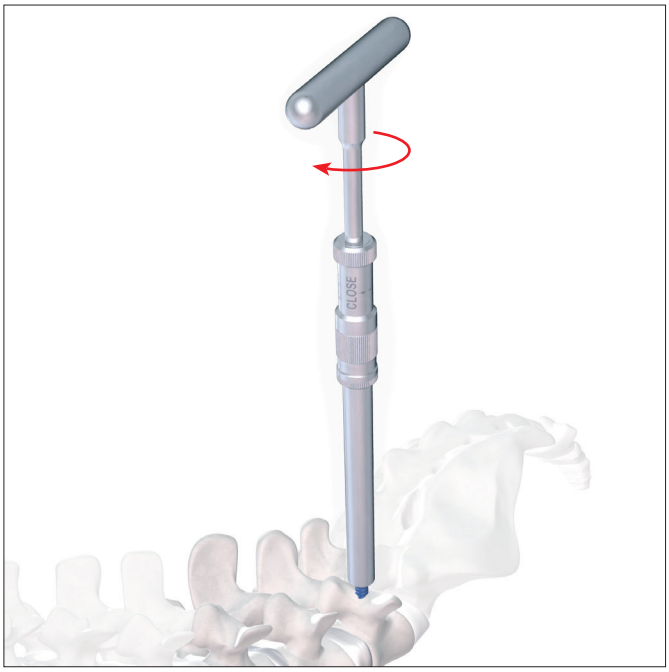
2. Insert screws into pedicles

Required instruments

03.607.001	Screwdriver, bihexagonal 3.0 mm, with T-Handle
03.607.003	USS II Polyaxial Holding Sleeve

Optional instruments

03.607.002	Screwdriver Shaft for USS II polyaxial cancellous bone screws with lengths ≥ 70 mm
03.607.006	USS II Polyaxial Handle



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.

Note: **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.**

Precaution: **For patients with suboptimal bone quality, the use of cancellous bone screws is recommended.**

3. Prepare seat for Polyaxial 3-D heads

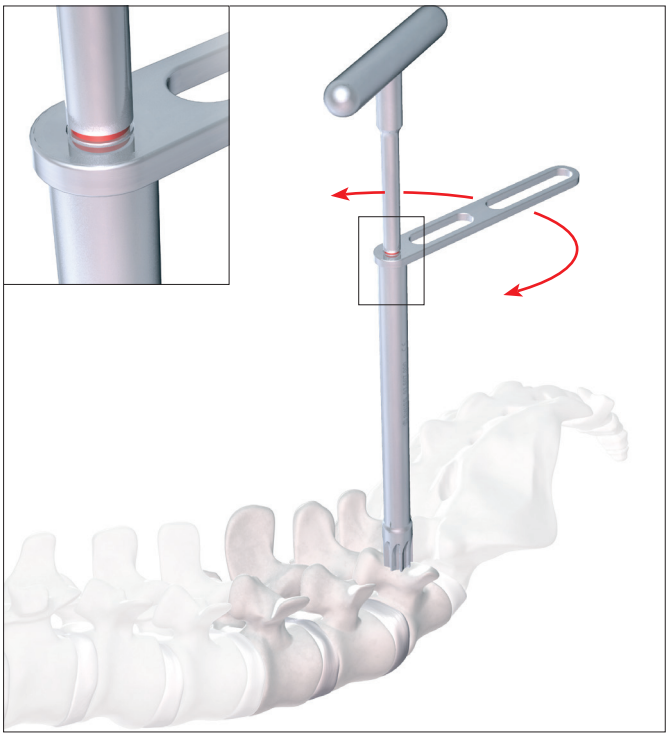
Required instruments

03.607.000	Reamer for USS II Polyaxial
03.607.001	Screwdriver, bihexagonal 3.0 mm, with T-Handle

Apply the Reamer guided by the Screwdriver over the head of the screw. To ensure free movement of the poly-axial 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.

Note: **Make sure that the Screwdriver is well inserted during the procedure.**



4. Insert 3-D heads

Required instruments

03.607.005	USS II Polyaxial Screw Holder
03.607.004	USS II Polyaxial Positioning Pliers for 3-D Heads

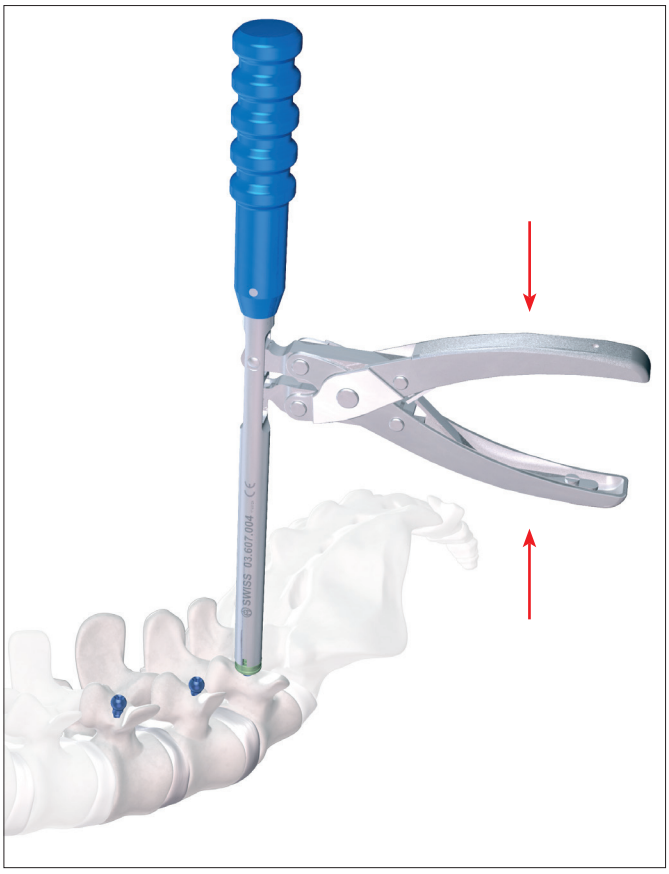
Precaution: **If more than one level has to be fused, it is recommended to check the required curvature of the rod before inserting the 3-D heads. Do so by aligning the Rod Template (388.870, from USS II Basic Instruments) with the screws (see step 5).**

The technique of head insertion is the same no matter which heads (for Ø 5.0 mm rods or for Ø 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.

Warning: **Once the polyaxial head is secured, if it is removed a new polyaxial head must be used.**



5. Select and insert rods

Required instruments

388.440	Holding Forceps with broad Tip, length 290 mm, for Rods Ø 6.0 mm

Optional instruments

388.960	Bending Pliers with Rolls for USS Rods Ø 6 mm, length 300 mm
03.607.006	USS II Polyaxial Handle
03.607.007	Positioner for Screw Holder

Determine the length and curvature of the rods. The ± 25° 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.

Warning: **Do not bend titanium rods more than 45°. Do not bend back and forth.**

Notes: **In multilevel cases, bend the rod according to the curvature of the rod template determined in step 4.**

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 03.607.006.

Note: **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**

Required instruments

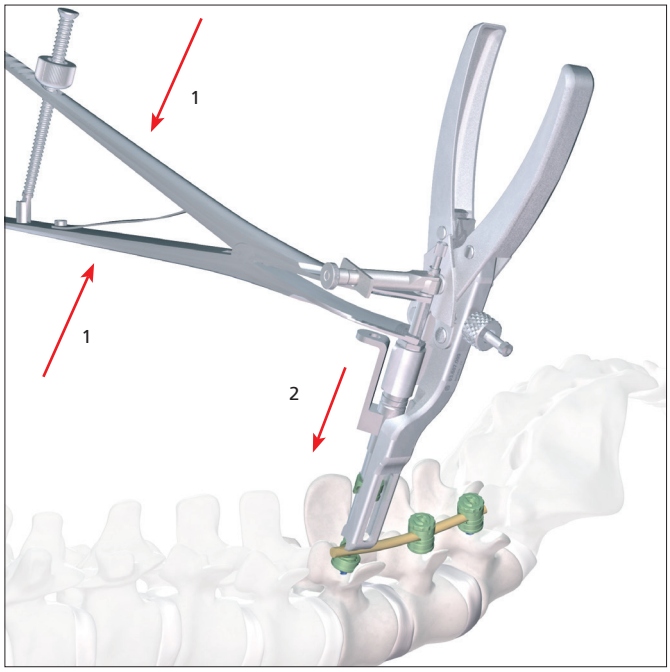
388.615	Counter Torque for Rod Introduction Pliers
03.607.009	USS II Polyaxial Rod Introduction Pliers
388.502	USS Sleeve Pusher
388.410	Spreader Forceps for USS and Click'X, length 330 mm

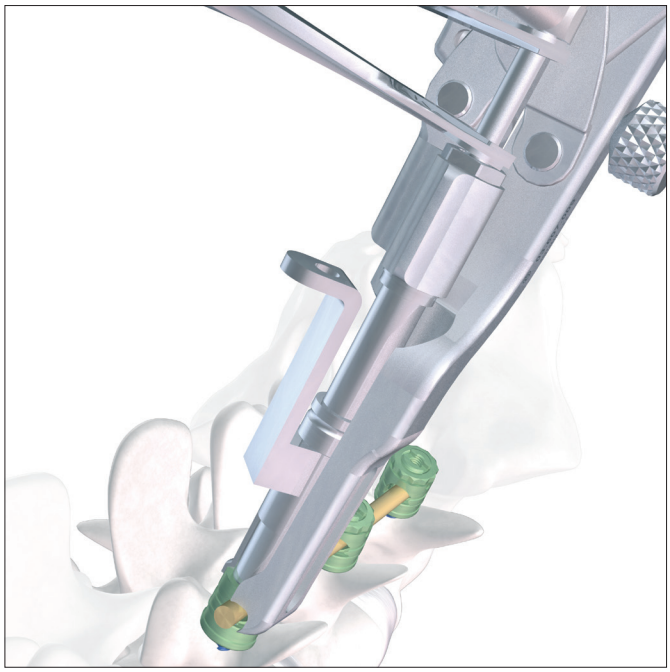
If necessary, use the Rod Introduction Pliers to align the rod with a screw head.

Precaution: **Never use the Rod Introduction Pliers without guidance provided by the Screw Holder.**

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 388.584 prior to final tightening (step 7).





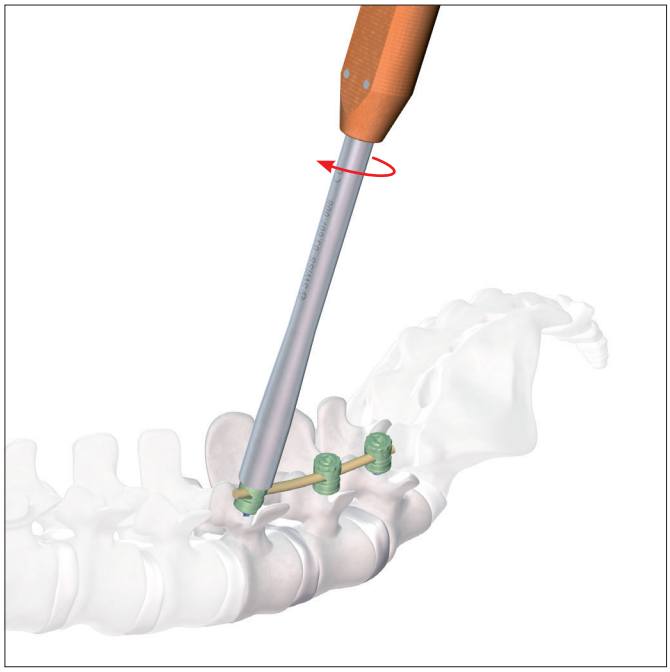
6. Insert sleeves and nuts

Required instruments

03.607.008	Socket Wrench, bihexagonal 11.0 mm, self-holding, with straight handle
03.607.006	USS II Polyaxial Handle
03.607.005	USS II Polyaxial Screw Holder

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.

Note: **For constructions with more than two screws on each side, start with the screw heads in the center.**



7. Tighten the nuts

Required instruments

388.584	Socket Wrench for twelve point nut, with L-Handle
388.143	Socket Wrench 5.0 mm, with T-Handle
03.607.005	USS II Polyaxial Screw Holder

Optional Instruments

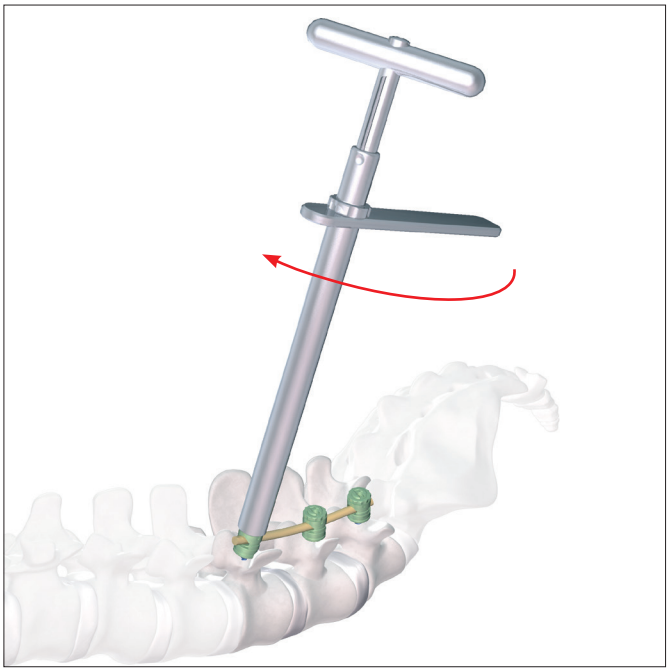
03.602.042	Torque-limiting Handle 12 Nm

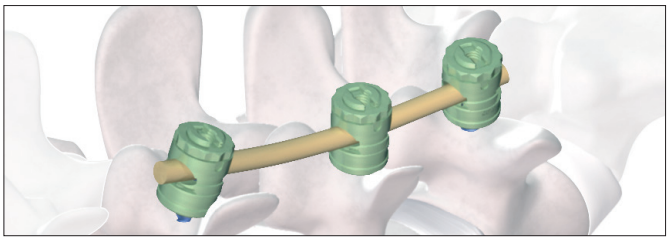
Use the Socket Wrench with L-Handle to final tighten the nuts. Counteract torque using the Socket Wrench with T-Handle placed over the Screw Holder.

Precaution: **Make sure to firmly tighten all nuts.**

Note: **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 (03.602.042) may be used instead of the Socket Wrench.**

Remove the Screw Holders when all the screws are finally tightened.





8. Remobilization and/or removal

Required instruments

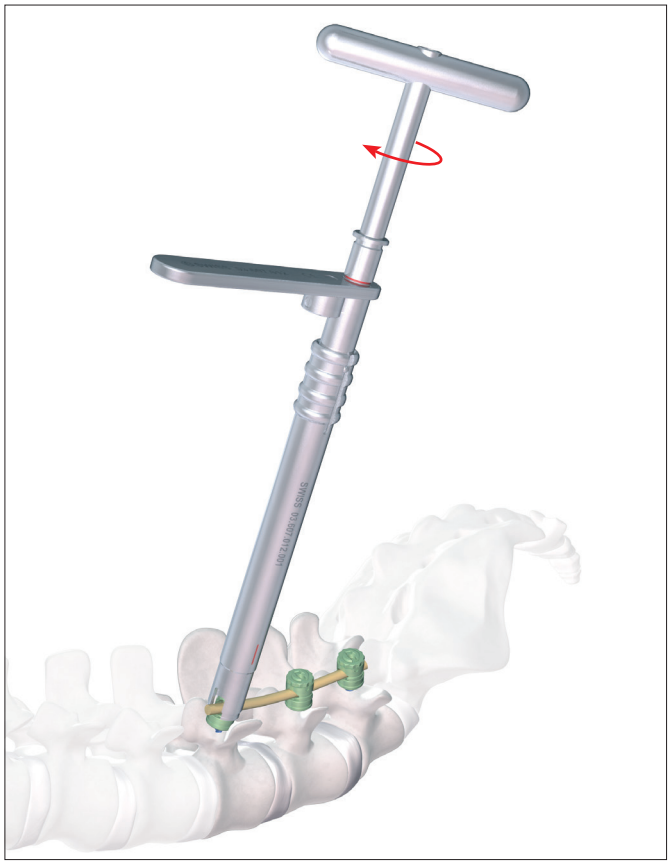
03.607.008	Socket Wrench, bihexagonal 11.0 mm, self-holding, with straight handle
03.603.108	Remobilization Tool for USS II Polyaxial
03.607.013	Stopping Sleeve for Remobilizing without Rod
03.607.014	Hollow Reamer B 12.6 mm for USS II Polyaxial
03.607.005	USS II Polyaxial Screw Holder

Precaution: **Always apply the Screw Holder as a guide.**

In the following situations, the USS II Polyaxial heads can be remobilized with the Remobilizing Instrument:

1. 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.

Warning: **Once the polyaxial head is secured, if it is removed a new polyaxial head must be used.**



2. Head without rod

Apply the Stop Sleeve over the polyaxial head. Then apply the Remobilizing Instrument as described before.

Note: 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.

Note: 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.

Indications and Contraindications

Please refer to the corresponding Instructions for Use for specific information on Intended use, Indications, Contraindications, Warnings and Precautions, Potential Adverse Events, Undesirable Side Effects and Residual Risks. Instructions for Use are available at www.e-ifu.com and/or www.depuysynthes.com/ifu.

Bibliography

1 Aebi M, Arlet V, Webb JK, (2007): AOSPINE Manual (2 vols), Stuttgart, New York: Thieme.

2 Aebi M, Thalgott JS, Webb JK (1998): AO ASIF Principles in Spine Surgery. Berlin: Springer.

DePuy Synthes
PART OF THE Johnson & Johnson FAMILY OF COMPANIES

Synthes GmbH
Eimattstrasse 3
4436 Oberdorf
Switzerland
Tel: +41 61 965 61 11

www.JnJMedicalDevices.com

Not all products are currently available in all markets.

This publication is not intended for distribution in the USA.

Surgical techniques are available as PDF files at
www.depuysynthes.com/ifu

SE_826386 (036.000.216; DSEM/SPN/0115/0260) EOS: 169843-210309. EMEA 03/21