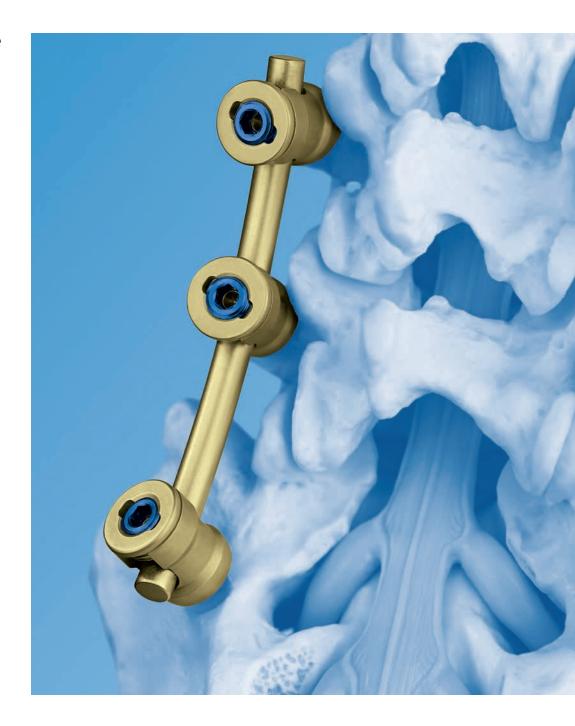
Click'X System. The complete toploading pedicle screw and rod system for the posterior stabilization of the lower back.



Surgical Technique

This publication is not intended for distribution in the USA.

Instruments and implants approved by the AO Foundation.



Image intensifier control

Warning

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	Overview	
	Indications and Contraindications	4
Product Information	Implants	5
	Instruments	7
Surgical Technique	General Surgical Technique	10
	Surgical Technique for Spondylolisthesis Reduction	32
	Remobilization and Removal of Undamaged Click'X Implants	38
	Removal of Click'X Implants with Damaged Hexagonal Socket	42

Two step locking mechanism

- Initial locking with locking cap for secure positiong of rod whilst screw heads remain mobile
- Final locking of construct with blue set screw for unconstrained locking without cross threading

Click'X Standard (Polyaxial with click-on head)

- Click-on mechanism for optimum field visualisation during segment preparation
- Polyaxial head for case specific manipulation







Click'X Standard Polyaxial Screws

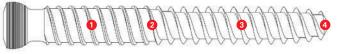




Intra-Op

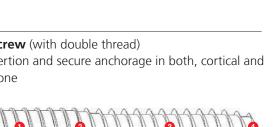
Post-Op

Dual core screw (with double thread) For rapid insertion and secure anchorage in both, cortical and cancellous bone



- Cylindrical zone with cortical bone thread profile
- **2** Short conical transition zone enhances pull-out strength
- 3 Cylindrical zone with cancellous bone thread profile
- **4** Threaded, round tip guarantees immediate bone grip





Click'X Preassembled

Preassembled polyaxial screw with high reliability and retaining force:

 allows controlled reduction of even very rigid spondylolisthesis

Click'X Monoaxial Rotational

Rotatable, preassembled head for easy positioning and manipulation:

- monosegmental instrumentation for Spondylolisthesis reduction
- multi-segmental instrumentation as stand alone or in combination with Click'X Standard screws





Pre-Op





Post-Op Spondylolisthesis correction with Click'X Preassembled

Jamman and a start of the start



Pre-Op

Click'X Monoaxial Rotational Screws



correction in the lumbar region



Click'X Preassembled Screws



The Click'X system is a posterior thoracolumbar pedicle screw system intended to provide precise and segmental stabilization of the spine in skeletally mature patients.

General indications

The implants can be used for the following indications in the area of the lower thoracic and lumbar spine

- Degenerative instabilities
- Instabilities following decompression
- Type A1 fractures and related types of the B and C group
- Type A2 and A3 fractures as well as similar fractures of the C group, if combined with an anterior intervention
- Tumors without anterior defect

Indications Spondylolisthesis

- Spondylolisthesis in the lumbar region

Notes:

- An anterior release is recommended for spondylolisthesis greater than grade I.
- An anterior release is essential for spondylolisthesis greater than grade II.
- A 360° fixation is recommended particularly after a major reduction.¹

Contraindications

- Deformities
- In fractures and tumors with severe anterior vertebral body disruption, an additional anterior support or column reconstruction is required.
- Osteoporosis

¹ Aebi M., Thalgott J.S., Webb J.K. (1998): AO ASIF Principles in Spine Surgery, Springer Verlag, Berlin, Chap. 7.2.2., p. 102 sq.

1. Screws

Click'X Standard, pedicle screw with dual core and click-on head, titanium alloy TAN (Ti Al6 Nb7)

Ø	Lengths	Colour
5.2 mm	30 – 60 mm	violet
6.2 mm	30 – 65 mm	blue
7.0 mm	30 – 65 mm	green
8.0 mm	30 – 65 mm	pink
9.0 mm	30 – 65 mm	turquoise
	5.2 mm 6.2 mm 7.0 mm 8.0 mm	5.2 mm 30 – 60 mm 6.2 mm 30 – 65 mm 7.0 mm 30 – 65 mm 8.0 mm 30 – 65 mm

3-D head for Click'X Standard pedicle screw

Art. No.	Material	
498.571	TAN	

Click'X Preassembled, pedicle screw with dual core, titanium alloy TAN (Ti Al6 Nb7)

Art. No.	Ø	Lengths	Colour
499.550–557	5.2 mm	30 – 65 mm	violet
498.986–993	6.2 mm	30 – 65 mm	blue
499.070,	7.0 mm	30 – 65 mm	green
498.994-			
499.000			
499.083–090	8.0 mm	30 – 65 mm	pink
499.560–567	9.0 mm	30 – 65 mm	turquoise

Click'X Monoaxial Rotational, pedicle screw with dual core

Available in TAV (Ti Al6 V4) only

Art. No.	Ø	Lengths	Colour
499.500V-507V	5.5 mm	30 – 65 mm	gold
499.510V-517V	6.2 mm	30 – 65 mm	blue
499.520V-527V	7.0 mm	30 – 65 mm	green

Click'X locking cap

Art. No.	Material	Drive
498.570	TAN	3.5 mm hexagonal
04.606.000	TAN	Stardrive T25









2. Rods

Click'X rod, curved, normalized, pure titanium

Art. No.	Ø	Lengths	
498.139–143	6 mm	45 – 85 mm	

USS rod, soft, pure titanium

Art. No.	Ø	Lengths
498.150–154	6 mm	50 – 150 mm

3. Transverse connectors

Cross-link clamp, for rods \oslash 6 mm, preassembled, titanium alloy (TAN)

Art. No.	Colour	
498.813	dark blue	

Cross-link, rod \varnothing 3.5 mm, titanium alloy (TAN)

Art. No.	Length	
496.930	40 mm	
496.950	50 mm	
496.970	60 mm	
496.980	70 mm	
498.120	80 mm	





388.537

or 388.539

Instruments	Instruments for pedicle preparation		Feeler for Screw Channel, \emptyset 2.3 mm,	
388.550	Pedicle Awl \varnothing 4.0 mm with Canevasit		length 275 mm, straight/curved	
	Handle, for Pedicle Screws B 5.0 to 7.0 mm	319.011	Depth Gauge for pedicle screws,	
	or		measuring range up to 110 mm	
388.656	Pedicle Awl \varnothing 4.0 mm with Silicone	or		
	Handle, for Pedicle Screws \varnothing 5.0 to 7.0 mm	357.789	Depth Gauge for pedicle screws \emptyset 4.2	
388.551	Pedicle Awl \varnothing 3.0 mm, length 230 mm,		to 9.0 mm	
	for Screws \emptyset 4.0 and 4.2 mm	311.602-606	Tap for Pedicle screws \varnothing 5.2 – 9.0 mm with dual core	
388.552	Pedicle Awl \varnothing 4.2 mm, with Silicone handle, for pedicle screws \varnothing 8.0 and 9.0 mm		with dual core	
		388.355	Reamer for Click'X Standard pedicle screws	
388.540	Pedicle Probe \varnothing 3.8 mm, with Canevasit	388.532	Reamer for preassembled pedicle screws	
	handle, for pedicle screws $arnothing$ 5.0 to 7.0 mm			
or				
388.655	Pedicle Probe \varnothing 3.7 mm with Silicone Handle,			
	for Pedicle Screws $arnothing$ 5.0 to 7.0 mm			
or				
388.498	Pedicle Probe with shaft, with Hexagonal			
	Quick Coupling \varnothing 6.0 mm			
388.657	Pedicle Probe \varnothing 3.8 mm, with Silicone handle,			

curved, for pedicle screws \varnothing 5.0 to 7.0 mm

Pedicle Probe \varnothing 5.0 mm, with Silicone handle, for pedicle screws \varnothing 8.0 and 9.0 mm

Pedicle Probe \varnothing 4.8 mm, with Canevasit handle, for pedicle screws \varnothing 8.0 and 9.0 mm

388.359

388.362

388.368

8

Instruments for screw insertion		Instruments for rod insertion	
314.131	Screwdriver for 3.5 mm Hexagonal Socket, with T-Handle	388.870	Bending Template $arnothing$ 6.0 mm, length 150 mm
or		or	
388.079	Screwdriver Shaft for 3.5 mm Hexagonal Socket, with Hexagonal Quick Coupling	388.902	Bending Template \varnothing 6.0 mm, length 150 mm, single use
	6.0 mm	388.960	Bending Pliers with Rolls for Rods
388.329	Screwdriver Shaft for 3.5 mm Hexagonal	500.500	\varnothing 6.0 mm
	Socket, long, with Hexagonal Quick	or	
	Coupling 6.0 mm	388.961	Bending Pliers with Rolls for Rods \varnothing 5.0 mm, with Radius Adjustment
388.364	Screwdriver for 3.5 mm Hexagonal Socket,		
	with T-Handle, for Click'X Preassembled pedicle screws	328.028	Rod Holding Forceps with scissors grip, straight, for Rods \varnothing 6.0 mm
314.064	Screwdriver Shaft 3.5 mm, long, with Hexagonal Quick Coupling 6.0 mm,	388.460	Rod Holding Forceps with scissors grip, angled, for Rods \varnothing 6.0 mm
	for preassembled Click'X Pedicle Screws	388.373/374	Holding Forceps for Rods, with narrow
or 314.067	Screwdriver Shaft 3.5 mm, short, with	300.373737374	jaws, straight/angled, length 300 mm
514.007	Hexagonal Quick Coupling 6.0 mm,		, , , , , , , , , , , , , , , , , , , ,
with	for preassembled Click'X Pedicle Screws	388.440	Holding Forceps for Rods \varnothing 6.0 mm, with wide jaws, length 290 mm
314.065 or	Holding Sleeve, long, for No. 314.064	388.114	Rod Pusher for Rods \varnothing 6.0 mm
314.068	Holding Sleeve, short, for No. 314.067	388.352	Rod Pusher for Click'X
with	<u> </u>		
314.066	Outer Sleeve for No. 314.065	388.369	Rod Pusher for Click'X, long
314.063	Holding Sleeve for Click'X Monoaxial Rotational pedicle screws		
314.069	Holding Sleeve for Click'X Preassembled pedicle screws		

Holding Sleeve, for Click'X Preassembled

Holding Sleeve for Click'X Standard pedicle

Positioning Holder for Click'X 3-D Head,

pedicle screws, for No. 388.364

with Disconnecting Device

screws

Instruments for locking cap insertion (hexagonal and Stardrive)

388.354	Screwdriver for Click'X Locking Cap, self-holding, with T- Handle
or	
388.365	Screwdriver for Click'X Locking Cap, self-holding, long, with T-Handle
388.366	Screwdriver for Click'X Locking Cap, long, with Knurled Handle
or	
388.375	Screwdriver for Click'X Locking Cap, with Knurled Handle

Instruments for locking cap insertion (Stardrive)

03.620.013 with	Locking Cap Driver with T-Handle
03.620.003	Screwdriver Shaft Stardrive, T25, with Hexagonal Coupling 6.0 mm

Instruments for distraction and compression

388.410	Distraction Forceps for pedicle screws
388.406	Distraction Forceps, hinged, with short tongues, for Click'X Standard pedicle screws
388.414	Distraction Forceps, hinged, with long tongues, for Click'X Preassembled pedicle screws
388.420	Compression Forceps, long, for pedicle screws, length 360 mm
or	
388.422	Compression Forceps, for pedicle screws, length 335 mm

Instruments for Spondylolisthesis reduction

388.358	Click'X Reduction Instrument
	for Spondylolisthesis

Removal instruments for damaged screw sockets

388.353	Extraction Pliers for Click'X
03.606.000	Centering sleeve for Rod Pusher for Click'X
03.606.001	Extraction Screw, conical, cannulated, for ClickX Preassembled
03.606.002	T-Handle, cannulated, for Extraction Screw for Click'X
03.606.003	Extraction Screw, conical, for Click'X
492.200	Kirschner Wire \varnothing 2.0 mm with trocar tip, length 150 mm, Titanium Alloy (TAV)
391.880	Vice Grip, length 180 mm

Removal instruments for locking caps

309.540	Extractor, with L-Handle, for damaged Click'X Locking Caps
309.541	Sleeve with L-Handle, for Extractor No. 309.540
321.200	Ratchet Wrench, for 11.0 mm hexagonal nut

Required instrument sets

01.606.203 Click'X Instruments in Vario Case

Optional instrument sets

105.078	Instruments for Pedicle Preparation
	in Vario Case

1

Open and prepare pedicles

a. Open pedicles and determine screw length

Required instruments

388.656	Pedicle Awl \varnothing 4.0 mm with Silicone Handle, for Pedicle Screws \varnothing 5.0 to 7.0 mm
388.655	Pedicle Probe \varnothing 3.7 mm with Silicone Handle, for Pedicle Screws \varnothing 5.0 to 7.0 mm

Note: Use image intensifier control to confirm instrument position.



Optional instruments

388.657	Pedicle Probe with Silicone handle, curved, for pedicle screws \varnothing 5.0 to 7.0 mm
388.551	Pedicle Awl \varnothing 3.0 mm, length 230 mm, for Screws \varnothing 4.0 and 4.2 mm
388.552	Pedicle Awl with Silicone handle, for pedicle screws \emptyset 8.0 and 9.0 mm
388.537	Pedicle Probe with Silicone handle, for pedicle screws \varnothing 8.0 and 9.0 mm

Locate pedicles as described in AO ASIF Principles in Spine Surgery. Use a Pedicle Awl to open the cortex of the pedicles (to a depth of 10 mm).

Continue opening the pedicles using a Pedicle Probe with markings at 30, 40 and 50 mm and determine the length of the Click'X pedicle screws.

Note: For correct fit of pedicle screws check diameter of Pedicle Awl and Pedicle Probe and corresponding screw size.



b. Measure screw channel (optional)

Required instruments

388.545/546	Feeler for Screw Channel, \varnothing 2.3 mm,
	length 275 mm, straight/curved

Optional instruments

319.011	Depth Gauge for pedicle screws,
	measuring range up to 110 mm

Measure the pedicle screw channel to determine the length of the pedicle screw with a Feeler for Screw Channel and make sure there are no perforations.

Note: Use image intensifier control to confirm instrument position.

c. Tapping (optional)

All Click'X screws are self-tapping, therefore it is not necessary to tap the pedicles. However, if tapping is preferred, use the appropriate size tap with tap handle.

Required instrument sets

105.078	Instruments for Pedicle Preparation in Vario Case
with 105.076	Taps for Pedicle Screws with Dual Core

Use the pedicle preparation set with the corresponding inserts for taps. Choose the tap according to screw type and size.

Follow the appropriate technique for screw insertion:

- Click'X Standard pedicle screws (step 2.1)
- Click'X Preassembled pedicle screws (step 2.2)
- Click'X Monoaxial Rotational pedicle screws (step 2.3)

2.1

Insert Click'X Standard pedicle screws

a. Insert Click'X Standard pedicle screw

Required instruments

388.079	Screwdriver Shaft for 3.5 mm Hexagonal Socket, with Hexagonal Quick Coupling 6.0 mm
with	
388.652	Ratchet Wrench with T-Handle
388.362	Holding Sleeve for Click'X Standard pedicle screws

Optional instruments

388.329	Screwdriver Shaft for 3.5 mm Hexagonal
	Socket, long, with Hexagonal Quick
	Coupling 6.0 mm

Attach the Holding Sleeve to a \emptyset 3.5 mm Hexagonal Screwdriver, ensuring that the Holding Sleeve is open to the red line. Load a Click'X Standard screw on the screwdriver assembly. Slide the Holding Sleeve over the head of the screw, and close the Holding Sleeve by rotating the knurled sleeve in the direction of the "close" arrow.

Insert the screw into the prepared pedicle.

Repeat for each screw.



Optional

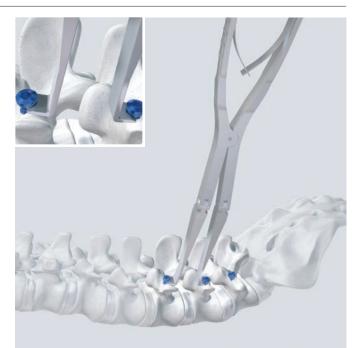
If desired, posterior interbody fusion may be performed at this time. Independent placement of the screws allows improved visualisation and access to the disc space.

Required instruments

388.406	Distraction Forceps, short tongues,
	for Click'X Standard pedicle screws

For interbody fusion, the use of Distraction Forceps facilitates the procedure (PLIF or T-PLIF). Insert the Distraction Forceps in closed position between both screws. Slowly open the Distraction Forceps while guiding the tips beneath the screw heads.

After interbody fusion procedure is completed remove instrument.



b. Prepare site for 3-D head

Required instruments

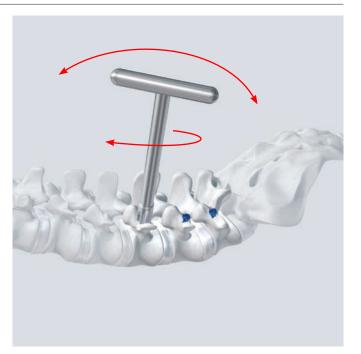
388.355Reamer for Click'X Standard pedicle screw	S
--	---

Place the Reamer over the Click'X Standard pedicle screw. Prepare the surrounding bone for the 3-D head, using rotating movements with the tilted reamer until any interfering bone has been removed.

Proper reaming will ensure that enough space is created around the 3-D head of the pedicle screw. This allows the head to align properly and enables stressfree instrumentation.

Repeat for each pedicle screw.

Note: Care should be taken when reaming the most superior (and inferior) level to maintain and protect the non-fused facet joints.



c. Attach 3-D head

Required instruments

388.368Positioning Holder for Click'X 3-D Head
with Disconnecting Device

Using the Positioning Holder, pick up a Click'X 3-D Head from the implant rack. Press or "click" the 3-D head securely over the Click'X Standard pedicle screw.

Press the button at the distal end of the instrument to push down the fuchsia conical element and release the 3-D head.

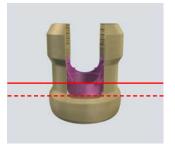
The 3-D head is still polyaxial at this time.

Note: If deeper insertion of the pedicle screw with attached 3-D head is required, make sure the 3-D head is not touching the bone surface as this will limit its polyaxial freedom and could lead to disengagement of the 3-D head.

Note: Prior to loading the 3-D head onto the Positioning Holder, verify that the fuchsia conical element in the 3-D head is not pressed down. If it is pressed down, it must be lifted in its upper position using the Extraction Pliers (388.353) as described on page 39.

Follow the appropriate technique for rod insertion: Insert rods (step 3 on page 24).





Correct

Incorrect

2.2

Insert Click'X Preassembled pedicle screws

a. Prepare site for 3-D head

Required instruments

388.532 Reamer for preassembled pedicle screws

Insert the tip of the Reamer into the probed hole. Prepare the surrounding bone for free mobility of the 3-D head, using rotating movements with the tilted Reamer until any interfering bone has been removed.

Repeat for each pedicle.

Note: Care should be taken when reaming the most superior (and inferior) level to maintain and protect the non-fused facet joints.



b. Insert Click'X Preassembled pedicle screws

Required instruments

388.079	Screwdriver Shaft for 3.5 mm Hexagonal Socket, with Hexagonal Quick Coupling 6.0 mm
with	
388.652	Ratchet Wrench with T-Handle
314.069	Holding Sleeve for Click'X Preassembled pedicle screws

Optional instruments

314.064	Screwdriver Shaft 3.5 mm, long, with Hexagonal Quick Coupling 6.0 mm, for preassembled Click'X pedicle screws
with 314.065 and	Holding Sleeve, long, for No. 314.064
314.066	Outer Sleeve for No. 314.065

Position the assembly of Screwdriver for 3.5 mm Hexagonal Socket and Holding Sleeve for Click'X Preassembled on the 3-D head and pick up a screw from the rack. Assure the Holding Sleeve is properly fitting in the 3-D head and that it is firmly tightened.

Insert the Click'X Preassembled pedicle screw into the prepared pedicle and withdraw the Holding Sleeve from the screw.

Repeat for each screw.



Optional

If desired, posterior interbody fusion may be performed at this time.

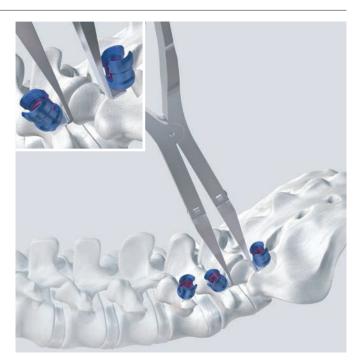
Required instruments

388.414 Distraction Forceps, hinged, with long tongues, for Click'X Preassembled pedicle screws

For interbody fusion, the use of Distraction Forceps facilitates the procedure (PLIF or T-PLIF). Insert the Distraction Forceps in closed position between both screws. Slowly open the Distraction Forceps while guiding the tips beneath the screw heads.

After interbody fusion procedure is completed remove instrument.

Follow the appropriate technique for rod insertion: Insert rods (step 3 on page 24).



2.3 Insert Click'X Monoaxial Rotational pedicle screws

a. Prepare site for rotational head

Required instruments

388.532 Reamer for preassembled pedicle screws

Insert the tip of the Reamer into the probed hole. Prepare the surrounding bone for free mobility of the rotational head, using rotating movements with the tilted Reamer until any interfering bone has been removed.

Repeat for each pedicle screw.

Note: Care should be taken when reaming the most superior (and inferior) level to maintain and protect the non-fused facet joints.



b. Insert Click`X Monoaxial Rotational pedicle screw

Required instruments

388.079	Screwdriver Shaft for 3.5 mm Hexagonal Socket, with Hexagonal Quick Coupling 6.0 mm
with	
388.652	Ratchet Wrench with T-Handle
314.063	Holding Sleeve for Click'X Monoaxial Rotational pedicle screws

Position the assembly of Screwdriver for 3.5 mm Hexagonal Socket and the Holding Sleeve for Click'X Monoaxial Rotational on the 3-D head and pick up a screw from the rack. Assure the Holding Sleeve is properly fitting in the rotational 3-D head and that it is firmly tightened.

Insert the screw into the prepared pedicle and withdraw the Holding Sleeve from the screw.



Repeat for each screw.

Optional

If desired, posterior interbody fusion may be performed at this time.

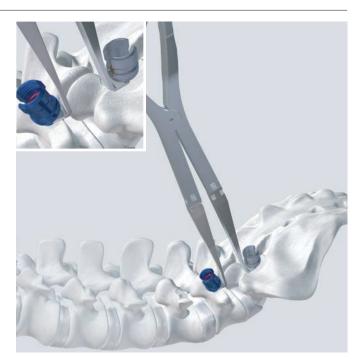
Required instruments

388.414 Distraction Forceps, hinged, with long tongues, for Click'X Preassembled pedicle screws

For interbody fusion, the use of Distraction Forceps facilitates the procedure (PLIF or T-PLIF). Insert the Distraction Forceps in closed position between both screws. Slowly open the Distraction Forceps while guiding the tips beneath the screw heads.

After interbody fusion procedure is completed remove instrument.

Follow the appropriate technique for rod insertion: Insert rods (step 3 on page 24).



3 Insert rods

a. Select and prepare rod

Required instruments

388.870	Bending Template \varnothing 6.0 mm, length 150 mm
388.961	Bending Pliers with Rolls for Rods \varnothing 5.0 mm, with Radius Adjustment

Determine the appropriate rod contour and length using the Bending Template. The polyaxial mobility of the 3-D head compensates for some lateral screw offset (except Click'X Monoaxial Rotational pedicle screws).

Select the appropriate length and, if necessary, bend the rod using Bending Pliers.

Note: Titanium rods must not be bent back and forth. Repeated bending can weaken the rod.

b. Insert rod

Required instruments

grij	d Holding Forceps with scissors o, straight/angled, for Rods 5.0 mm
------	---

Insert the rod into the 3-D or rotational head using Rod Holding Forceps.

Note: Before inserting a rod, ensure each of the 3D heads can move freely. If there is limited polyaxial movement, back out the screw assembly by turning counterclockwise until full range of motion is obtained.



c. Push rod into 3-D head

Required instruments

388.352 Rod Pusher for Click'X

Optional instruments

388.114	Rod Pusher for Rods \varnothing 6.0 mm
388.369	Rod Pusher for Click'X, long

Using a Rod Pusher, push the rod firmly into the 3-D or rotational head. For constructs with two or more levels, it is recommended to begin with the central 3-D head.



4 Attach locking caps

Required instruments

388.375	Screwdriver for Click'X Locking Cap, with Knurled Handle
388.352	Rod Pusher for Click'X

Optional instruments

388.366	Screwdriver for Click'X Locking Cap, long, with Knurled Handle
388.369	Rod Pusher for Click'X, long

Using a Screwdriver for Click'X Locking Cap, pick up a locking cap from the implant rack. Ensure the screwdriver tongs fit firmly into the slots of the locking cap.

With the Rod Pusher in place, insert the Locking Cap and **finger tighten with thumb and forefinger** to capture the rod within the head.

The head will retain its polyaxial resp. rotatable mobility.

Note: Use of the Rod Pusher ensures correct alignment and minimizes cross-threading of the locking cap.

Repeat for the remaining pedicle screws, ensuring that all locking caps are attached.



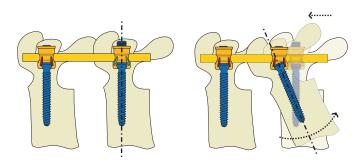
5 Compress or distract

Compression and distraction can be applied in two different modes:

a. Lordotic manipulation:

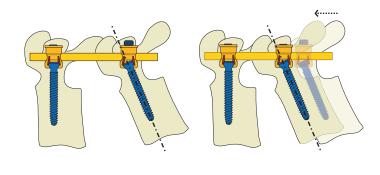
With mobile polyaxial 3-D heads the angle of the pedicle screws and the rod is variable. The trapezium shaped disc space between the vertebral bodies may be compressed or distracted **at the posterior end only** to reposition the curvature of the lumbar spine.

Note: With Click'X Monoaxial Rotational pedicle screws lordotic compression is not possible as polyaxial head movement is not possible. The heads will not align to the rod and might not be locked properly.



b. Parallel manipulation:

With fixed 3-D resp. rotational heads the angle of the pedicle screw and the rod is fixed. The trapezium shaped disc space between the vertebral bodies may be compressed or distracted with a **linear load distribution over the endplates to reposition the height** of a motion segment.

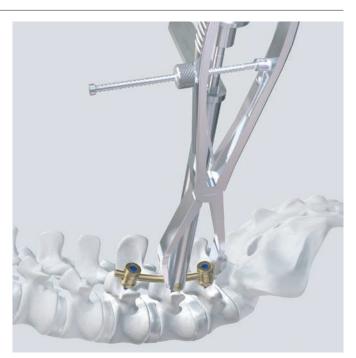


Locked
Unlocked

a. Lordotic manipulation: Compress or distract with mobile 3-D heads to reposition curvature

Required instruments

388.422	Compression Forceps, for pedicle screws
388.410	Distraction Forceps for pedicle screws
388.354	Screwdriver for Click'X Locking Cap, self-holding, with T- Handle
388.079	Screwdriver Shaft for 3.5 mm Hexagonal Socket, with Hexagonal Quick Coupling 6.0 mm
with	
388.652	Ratchet Wrench with T-Handle
388.352	Rod Pusher for Click'X



Optional instruments

388.365	Screwdriver for Click'X Locking Cap, self-holding, long, with T-Handle
388.329	Screwdriver Shaft for 3.5 mm Hexagonal Socket, long, with Hexagonal Quick Coupling 6.0 mm
388.369	Rod Pusher for Click'X, long

Use Compression Forceps to achieve compression, or Distraction Forceps to achieve distraction. Once the desired compression or distraction is achieved, keep it and simultaneously tighten the blue set screws by inserting a Screwdriver for 3.5 mm Hexagonal Socket through the Rod Pusher, using the Rod Pusher as countertorque.

Repeat for each level.

Compression

Note: Compression or distraction with mobile 3-D heads is only possible if the blue set screw of the locking caps has not been tightened yet.

b. Parallel manipulation: Compress or distract with fixed 3-D heads to reposition height of disc space

Required instruments

388.422	Compression Forceps
388.410	Distraction Forceps for pedicle screws
388.354	Screwdriver for Click'X Locking Cap, self-holding, with T-Handle
388.079	Screwdriver Shaft for 3.5 mm Hexagonal Socket, with Hexagonal Quick Coupling 6.0 mm
with	
388.652	Ratchet Wrench with T-Handle
388.352	Rod Pusher for Click'X



Distraction

Optional instruments

388.365	Screwdriver for Click'X Locking Cap, self-holding, long, with T-Handle
388.329	Screwdriver Shaft for 3.5 mm Hexagonal Socket, long, with Hexagonal Quick Coupling 6.0 mm
388.369	Rod Pusher for Click'X, long

Restore proper lordosis, then place a Screwdriver for 3.5 mm Hexagonal Socket through the Rod Pusher. Tighten the blue set screw while using the Rod Pusher as countertorque.

Repeat for each screw.

Place the Screwdriver for Click'X locking cap through the Rod Pusher and onto the assembly, inserting the prongs into the locking cap. Insert a 3.5 mm Hexagonal Socket through the shaft of the Screwdriver for Click'X locking caps. Loosen the locking cap set screw while counteracting torque with both the Rod Pusher and the locking cap screwdriver. This will prevent the locking cap from loosening.

Use Compression Forceps to achieve compression or Distraction Forceps to achieve distraction. Once the desired compression or distraction is achieved, keep it and simultaneously retighten the blue set screws with a 3.5 mm Hexagonal Screwdriver.

6 Final tightening

Required instruments

388.079	Screwdriver Shaft for 3.5 mm Hexagonal Socket, with Hexagonal Quick Coupling 6.0 mm
388.352	Rod Pusher for Click'X

Optional instruments

388.329	Screwdriver Shaft for 3.5 mm Hexagonal Socket, long, with Hexagonal Quick Coupling 6.0 mm
388.369	Rod Pusher for Click'X, long

Place the Rod Pusher over the 3-D resp. rotational head. Using a 3.5 mm Hexagonal Screwdriver, thighten the set screw until the audible "screeching" noise, which indicates the proper locking of the assembly.

Repeat for all locking caps.

Optional

If desired, a torque-limiting handle may be used. Attach a screwdriver shaft to the handle and tighten until the audible "click" noise.

Optional

If desired, transverse connectors may be added. They are intended to stabilize the construct and increase stability.



Surgical Technique for Spondylolisthesis Reduction

Required instrument sets

01.606.203	Click'X Instruments in Vario Case
01.606.303	Spondylolisthesis Reduction Instruments in Vario Case

Optional instrument sets

105.078	Instruments for Pedicle Preparation
	in Vario Case

Spondylolisthesis reduction can be achieved using the Click'X Spondylolisthesis Reduction Instruments.

For pedicle screw placement refer to the surgical technique described earlier in this brochure.

For a single level spondylolisthesis reduction two methods are possible:

a. Bi-segmental instrumentation

All types of Click'X screws can be used cranial and caudal to the slipped vertebra. For the slipped vertebra itself, the use of Click'X Preassembled pedicle screws is mandatory.



b. Mono-segmental instrumentation

Since bending strength is limited with all polyaxial pedicle screws, use only Click'X Monoaxial Rotational pedicle screws caudal (or cranial) to the slipped vertebra. **For the slipped vertebra itself, the use of Click'X Preassembled pedicle screws is mandatory.**

The surgical technique described shows a bi-segmental instrumentation of a spondylolisthesis on L5/S1 with Click'X Standard pedicle screws cranial and caudal to the slipped vertebrae.



1 Insert Click'X screws

Follow steps 1 and 2 described in the surgical technique for Click'X screws.

Insert Click'X Standard, Preassembled or Monoaxial Rotational pedicle screws in the adjacent vertebrae.

Insert Click'X Preassembled pedicle screws into the affected level.

Note: Care should be taken when reaming the most superior (and inferior) level to maintain and protect the non-fused facet joints.



2 Insert rods

Follow step 3 described in the surgical technique for Click'X screws

Select the appropriate rod length and insert into the 3-D heads. Place locking caps in the 3-D heads of the cranial and caudal vertebrae.

Tighten the caudal set screws only. This will prevent the slippage of the rod during the subsequent reduction.

Note: The Click'X Preassembled pedicle screws are pulled right up to the rod during reduction. The reduction track is determined by the curve of the rod and the position resp. insertion depth of the screws.



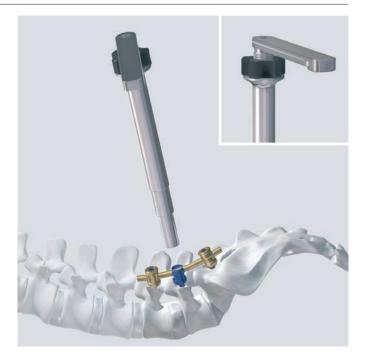
3 Apply reduction instruments

a. Attach reduction instruments

Required instruments

388.358	Click'X Reduction Instrument for
	Spondylolisthesis

Check that the black nut on each Reduction Instrument is near the handle of the instrument. Place reduction instruments bilaterally on the 3-D heads in the level to be reduced. Slide the guiding tubes down the rods, ensuring that the 3-D heads are engaged.



b. Reduce vertebral body

Required instruments

388.358

Click'X Reduction Instrument for Spondylolisthesis

Rotate the nuts on each instrument simultaneously in clockwise direction to gradually pull each screw to the rod. Once the red line appears on the thread, the rod is fully seated in the 3-D head.

Note: Distraction between L5/S1 or L4/L5 may be required prior to reduction. Please refer to step 2.2 described in the general surgical technique for Click'X screws.



4

Assemble construct

a. Attach locking caps on remaining 3-D heads

Required instruments

388.366	Screwdriver for Click'X Locking Cap, long, with Knurled Handle
388.358	Click'X Reduction Instrument for Spondylolisthesis

Remove the inner tube of the Reduction Instruments.

Use the long Screwdriver for Click'X Locking Cap to insert the locking caps. **Finger tighten with thumb and forefinger** each locking cap while applying countertorque with the Reduction Instrument.



b. Remove reduction instruments

Fully unscrew the black nuts on both Reduction Instruments, push the guiding tubes upwards and remove the instruments.

5 Compress or distract

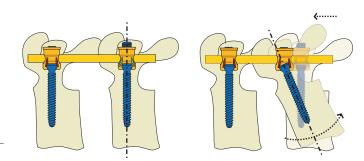
Follow step 5 described in the general surgical technique for Click'X screws

Compression and distraction can be applied in two different modes:

a. Lordotic manipulation:

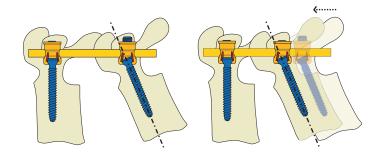
With mobile polyaxial 3-D Heads the angle of the pedicle screws and the rod is variable. The trapezium shaped disc space between the vertebral bodies may be compressed or distracted **at the posterior end only** to reposition the **curvature** of the lumbar spine.

Note: With Click'X Monoaxial Rotational pedicle screws lordotic compression is not possible as polyaxial head movement is not possible. The heads will not allign to the rod and might not be locked properly.



b. Parallel manipulation:

With fixed 3-D resp. rotational heads the angle of the pedicle screw and the rod is fixed. The trapezium shaped disc space between the vertebral bodies may be compressed or distracted with a **linear load distribution over the endplates** to reposition the **height** of a motion segment.



Locked

6

Apply final tightening

Follow step 6 described in the general surgical technique for Click'X screws.

Optional

If desired, transconnectors may be added. They are intended to stabilize the construct and increase stability.



Remobilization and Removal of Undamaged Click'X Implants

Required instrument sets

01.606.203	Click'X Instruments in Vario Case
or	
01.606.103	Click'X System Removal Set in Vario Case

1

Removal of Click'X Locking Cap

Required instruments

314.131	Screwdriver for 3.5 mm Hexagonal Socket, with T-Handle
388.352	Rod Pusher for Click'X
03.606.000	Centering Sleeve for Rod Pusher for Click'X

Place the Rod Pusher over the 3-D head. Use the assembly of Rod Pusher, Centering Sleeve and Screwdriver to loosen the blue set screw of the locking cap while counteracting torque with the Rod Pusher.

Note: Never use a self-holding Screwdriver for Click'X Locking Cap (e.g. 388.354) to loosen or remove the locking caps.



2 Remobilization of Click'X 3-D head

Required instruments

388.353

Extraction Pliers for Click'X

Remove the rod. The 3-D head has to be remobilized with the Extraction Pliers. Introduce the pliers deeply into the head and compress the handle. Check if the 3-D head is mobile.



3.1 Removal of Click'X Standard pedicle screw

Required instruments

314.131	Screwdriver for 3.5 mm Hexagonal Socket, with T-Handle
388.362	Holding Sleeve for Click'X Standard pedicle screws

After remobilizing the 3-D head (steps 1 and 2), remove it by toggling the head while pulling.

Use the assembly of Holding Sleeve for Click'X Standard screws and Screwdriver. Close the Holding Sleeve, assure firm locking and remove the Click'X Standard pedicle screw.

Note: Do not reuse removed 3-D heads.



3.2 Removal of Click'X Preassembled pedicle screw

Required instruments

314.131	Screwdriver for 3.5 mm Hexagonal Socket, with T-Handle
314.069	Holding Sleeve for Click'X Preassembled pedicle screws

After remobilizing the 3-D head (steps 1 and 2) use the assembly of Holding Sleeve for Click'X Preassembled screws and Screwdriver. Close the Holding Sleeve, assure firm locking and remove the Click'X Preassembled pedicle screw.



3.3 Removal of Click'X Monoaxial Rotational pedicle screw

Required instruments

314.131	Screwdriver for 3.5 mm Hexagonal Socket, with T-Handle
314.063	Holding Sleeve for Click'X Monoaxial Rotational pedicle screws

Remove locking cap and rod. Use the assembly of Holding Sleeve for Click'X Monoaxial Rotational screws and Screwdriver. Assure firm locking of the Holding Sleeve and remove the Click'X Monoaxial Rotational pedicle screw.



Removal of Click'X Implants with Damaged Hexagonal Socket

Required instrument sets

01.606.103

Click'X System Removal Set in Vario Case

Note: Click'X removal with the help of an extraction screw is only applicable on screws with damaged hexagonal sockets. For screws with intact hexagonal sockets, use the standard screwdrivers (see preceding part).

1.1

Removal of Click'X Locking Cap with damaged hex socket using an extraction screw

Required instruments

388.352	Rod Pusher for Click'X
03.606.000	Centering Sleeve for Rod Pusher for Click'X
03.606.002	T-Handle, cannulated, for Extraction Screw for Click'X
03.606.003	Extraction Screw, conical, for Click'X

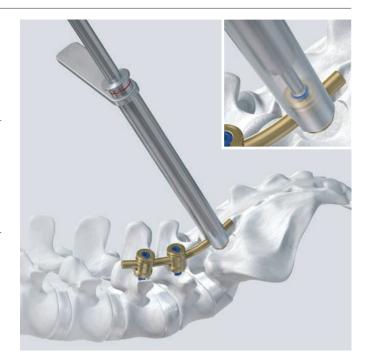
Put the Rod Pusher over the Click'X head and make sure that it is aligned over the head (if not remove disturbing structures around the head). Insert the Centering Sleeve with red marking into the Rod Pusher. Mount the Extraction Screw with red marking on the T-Handle and introduce the assembly through the Centering Sleeve.



Turn the handle counter-clockwise to secure the Extraction Screw in the damaged socket of the locking cap set screw. Counteract torque with the Rod Pusher. Continue turning to loosen the blue set screw and go on until the locking cap is removed.

Notes:

- Never use a self holding Screwdriver for Click'X Locking Cap (e.g. 388.354) to loosen or remove the locking caps.
- Only the Extraction Screw with red marking is intended for the removal of locking caps, never use the Cannulated Extraction Screw.



Removal of Click'X Locking Cap with damaged hex socket using locking cap removal tools

Required instrument sets

187.340	Extraction Instrument Set for Damaged
	Click'X Locking Caps, in Vario Case

Required instruments

309.540	Extractor, with L-Handle, for damaged Click'X Locking Caps
309.541	Sleeve, with L-Handle, for Extractor No. 309.540
321.200	Ratchet Wrench, for 11.0 mm hexagonal nut

Note: The locking cap removal tools can be used to remove the locking cap from a Click'X assembly. They are used in revision surgery in which the blue locking cap set screw has been damaged. These tools damage the 3-D heads. After removing the locking cap, the Click'X screws and 3-D heads must be replaced.

Insert the Extractor, with L-Handle, for damaged Click'X Locking Caps through the Sleeve with L-Handle. Place the distal end of the extractor on the locking cap and slide the sleeve down over the rod. Hand-tighten the nut of the extractor. Place the Ratchet Wrench on the 11 mm nut so that the word "ON" is visible on the body of the wrench. Use the Ratchet Wrench to tighten the nut.

While holding the Sleeve with L-Handle, for Extractor No. 309.540 in place, turn the extractor counterclockwise, until there is no resistance. Remove the extractor and sleeve from the assembly. Remove the locking cap from the extractor. Using the Ratchet Wrench in the "OFF" position, turn the nut counterclockwise until the cap is released.





Removal of Click'X Standard pedicle screw with damaged hex socket

Required instruments

388.362	Holding Sleeve for Click'X Standard pedicle screws
03.606.002	T-Handle, cannulated, for Extraction Screw for Click'X
03.606.003	Extraction Screw, conical, for Click'X
391.880	Vice Grip, length 180 mm

Assure that the 3-D head is remobilized as described in step 2 on page 39. Remove the 3-D head by toggling sideways and pulling upwards, either by hand or with the vice grip.

Assemble the Holding Sleeve, the T-Handle and the Extraction Screw with red marking. Place the Holding Sleeve over the Click'X Standard pedicle screw and close it by assuring firm locking. If the Holding Sleeve fails to align the assembly, remove disturbing bone structure. Turn the T-Handle counter-clockwise to secure the Extraction Screw in the damaged socket. Continue turning to remove the pedicle screw.



Removal of Click'X Preassembled pedicle screw with damaged hex socket

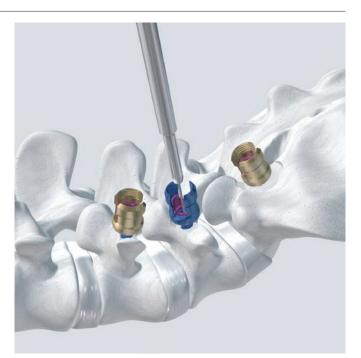
Required instruments

492.200	Kirschner Wire $arnothing$ 2.0mm with trocar tip, length 150 mm, Titanium Alloy (TAV)
03.606.001	Extraction Screw, conical, cannulated, for ClickX
03.606.002	T-Handle, cannulated, for Extraction Screw for Click'X

Assure that the 3-D head is remobilized as described in step 2 on page 39.

Insert the Kirschner wire into the central hole of the hexagonal socket of the Click'X Preassembled pedicle screw. Assemble the T-Handle and the Cannulated Extraction Screw. Slide the assembly over the Kirschner wire and turn the T-Handle counter-clockwise to secure the Extraction Screw in the damaged socket. Continue turning to remove the implant.

Note: The Kirschner wire must be used to provide proper guidance of the Cannulated Extraction Screw.



Removal of Click'X Monoaxial Rotational pedicle screw with damaged hexagonal socket

Required instruments

314.063	Holding Sleeve for Click'X Monoaxial Rotational pedicle screws
03.606.002	T-Handle, cannulated, for Extraction Screw for Click'X
03.606.003	Extraction Screw, conical, for Click'X

Assemble the Holding Sleeve, the T-Handle and the Extraction Screw with red marking. Place the assembly on the grey monoaxial head and close by assuring firm locking. If the Holding Sleeve does not fit over the head, remove disturbing bone structure. Turn the T-Handle counter-clockwise to secure the Extraction Screw in the damaged hexagonal socket. Continue turning to remove the pedicle screw.



3 Detaching of implants from Extraction Screws

Required instruments

391.880 Vice Grip, length 180 mm

Hold the locking cap firmly with the Vice Grip and turn the Extraction Screw clock-wise (as a normal screw would be tightened).

Note: Carefully inspect the thread of the Extraction Screw. Do not reuse if the screw is damaged (see 035.000.090 "Care and Maintenance of Synthes Instruments").

4

Failure of Extraction Screw in damaged hex socket

Required instruments

309.5045	HSS Drill Bit Ø 3.5 mm, sterile
_	Power tool with Jacobs chuck

If removal with the help of an Extraction Screw fails at first instance, the grip of the Extraction Screw in the damaged hexagonal socket can be enhanced by drilling further into the hexagonal socket with an HSS Drill Bit. Repeat removal step by step with an intact Extraction Screw.



Synthes GmbH Eimattstrasse 3 4436 Oberdorf Switzerland Tel: +41 61 965 61 11 Fax: +41 61 965 66 00 www.depuysynthes.com

Not all products are currently available in all markets.

This publication is not intended for distribution in the USA.

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

