ArcoFix. Anterior-only reduction plate.

Technique Guide

SYNTHES®

Instruments and implants
approved by the AO Foundation

Table of Contents

Image intensifier control

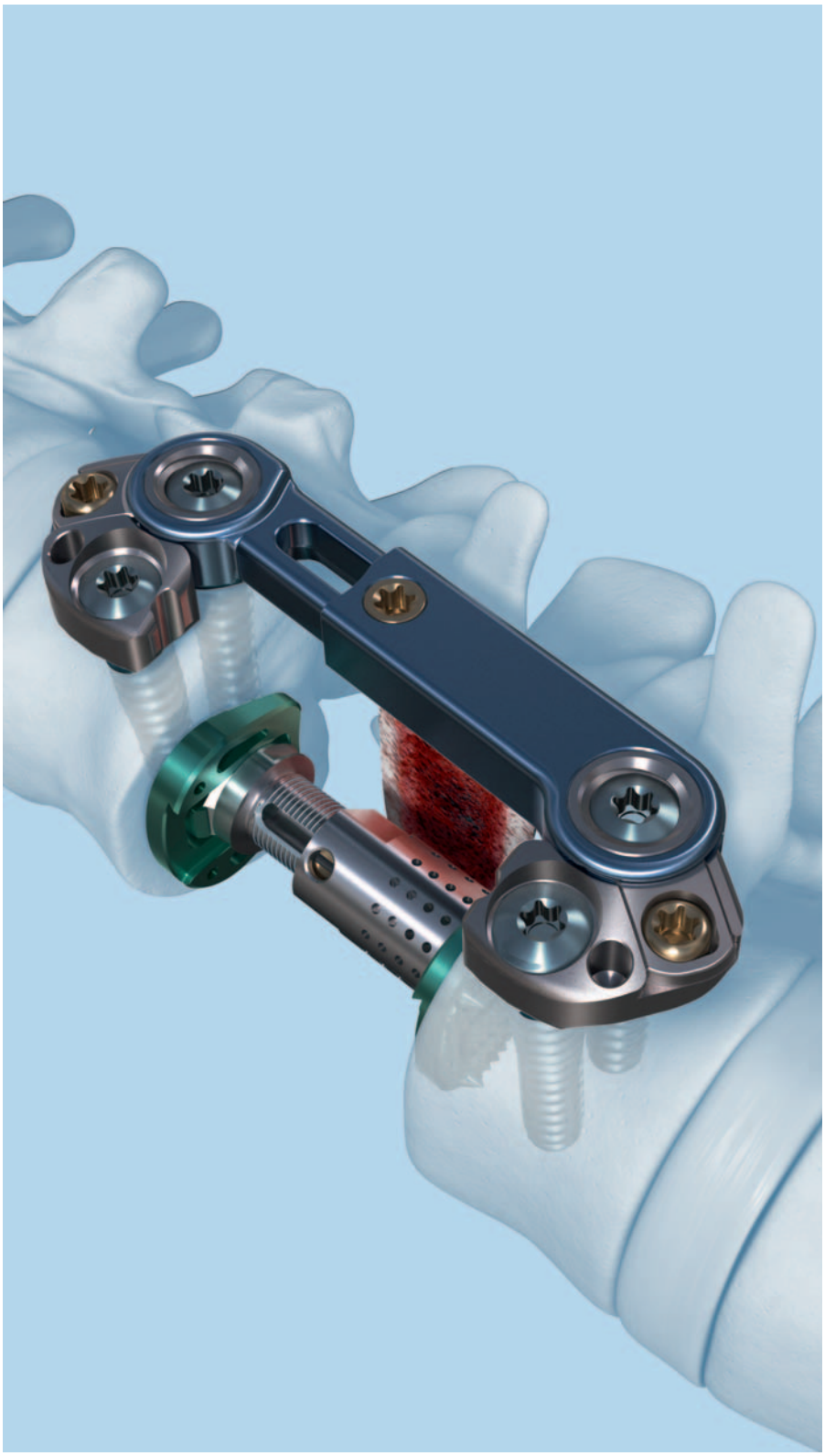
Warning
This description alone does not provide sufficient background for direct use of the instrument set. Instruction by a surgeon experienced in handling these instruments is highly recommended.

Reprocessing, Care and Maintenance of Synthes Instruments
For general guidelines, function control and dismantling of multi-part instruments, please refer to: www.synthes.com/reprocessing

Important note on servicing Torque-limiting T-handle, 7 Nm (Art. 321.133)
Torque-limiting instruments must be serviced:
- Once every 6 months or after every 50 autoclave cycles, whichever occurs first
- If you suspect that the instrument is out of calibration servicing is handled through normal sales channels of the subsidiary in the respective country. (see also packaging insert SE_038626)

Anterior-only approach

- Comprehensive fracture treatment from anterior only
- Minimized trauma
- Reduced surgery time and blood loss
- Fast recovery, early return to work
- Synex II inserted past ArcoFix



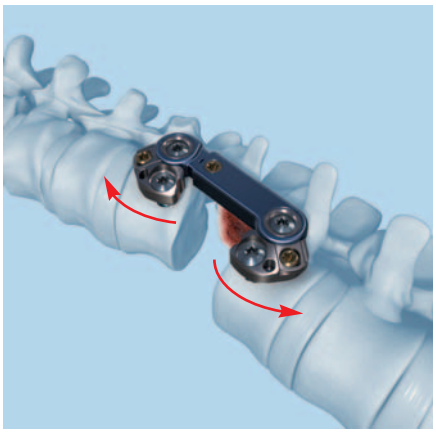
Key Instruments

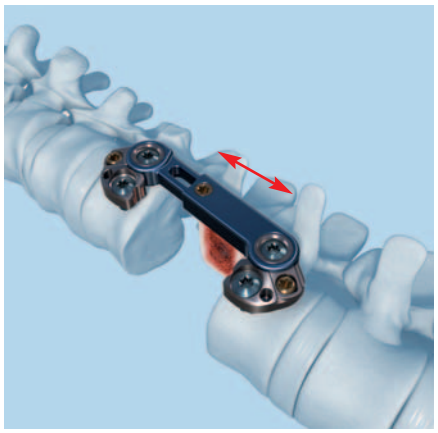
Only three key instruments to perform surgery:
Positioning (1)
Screw insertion (2)
Active kyphosis correction (3)

Active kyphosis correction and restoration of vertebral body height

- Direct visual control of correction
- Individual cranial and caudal angle correction
- Deliberate and continuous adjustment of vertebral body height

Active kyphosis correction can be done all in once or step by step





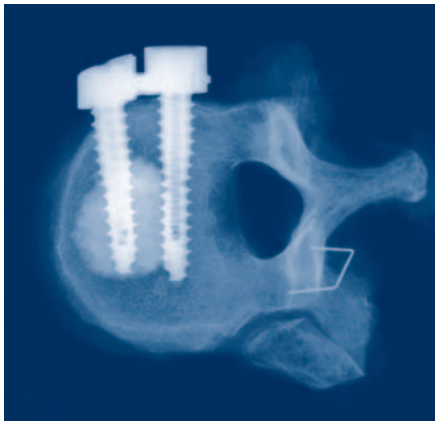
Synergy to Synex II

- Angled spreader top allows to insert ArcoFix past Synex II
- Choice of endplate angulations enables a perfect match of the angle correction achieved with ArcoFix
- Identical handling of ArcoFix reduction instrument and Synex II spreader

Instead of Synex II any other legally marketed Vertebral Body Replacement Device (e.g. Synex, SynMesh) or bone graft can be used together with ArcoFix at the discretion of the surgeon.

Screw augmentation with Vertecem Vertebroplasty System

- Better screw anchorage
- Additional implant fixation
- Prevents screw cut-through



AO Principles

In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation[1]. They are:

– Anatomic reduction
– Stable internal fixation
– Preservation of blood supply
– Early, active mobilization

The fundamental aims of fracture treatment in the limbs and fusion of the spine are the same. A specific goal in the spine is returning as much function as possible to the injured neural elements[2].

AO Principles as applied to the spine[3]

Anatomic reduction
In the spine, this means reestablishing and maintaining the natural curvature and the protective function of the spine. By regaining this natural anatomy, the biomechanics of the spine can be improved, and a reduction of pain can be experienced.

Stable internal fixation
In the spine, the goal of internal fixation is to maintain not only the integrity of a mobile segment, but also to maintain the balance and the physiologic three-dimensional form of the spine. A stable spinal segment allows bony fusion at the junction of the lamina and pedicle.

Preservation of blood supply
The proper atraumatic technique enables minimal retraction or disturbance of the nerve roots and dura, and maintains the stability of the facet joints. The ideal surgical technique and implant design minimize damage to anatomical structures, i.e. facet capsules and soft tissue attachments remain intact, and create a physiological environment that facilitates healing.

Early, active mobilization
The ability to restore normal spinal anatomy may permit the immediate reduction of pain, resulting in a more active, functional patient. The reduction in pain and improved function can result when a stable spine is achieved.

1 Müller ME, Allgöwer M, Schneider R, Willenegger H (1995) Manual of Internal Fixation. 3rd, exp. a. completely rev. ed. 1991. Corr. 3rd printing. Berlin, Heidelberg, New York: Springer
2 Ibid.
3 Aebi M, Arlet V, Webb JK (2007) AOSPINE Manual (2 vols), Stuttgart, New York: Thieme

Indications and Contraindications

ArcoFix is an implant and instrument system for the anterior stabilization of the thoracolumbar spine (T8–L4), e.g. after discectomies and partial or complete corpectomies. It can be used in combination with a bone graft or a vertebral body replacement such as Synex or Synex II. ArcoFix was specifically designed to be combined with Synex II.

Indications

- A-type fractures with canal clearance
- Pathological fractures with intact posterior ligamentous complex
- Tumor-related surgeries
- Traumatic kyphosis that can be adequately reduced and secured from anterior
- Additional anterior fixation in cases where anterior stabilization and/or correction is important
- Osteoporosis is only indicated when used concurrently with PMMA-Cement indicated for internal spinal fixation supplementation

Contraindications

- General contraindications against anterior surgery (e.g. patient condition, advanced age)
- Severe osteoporosis
- Correction of scoliotic deformities
- Fractures with severe injury of the posterior structures
- Degenerative disease

Estimation of implant height

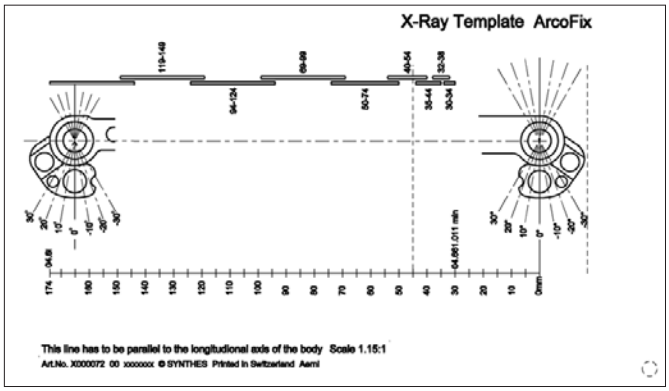
Template	
X000072	X-Ray Template for ArcoFix Implants

Implant size can be estimated preoperatively based on x-ray/CT scan information and intraoperatively confirmed based on measurements.

For preoperative estimation of height and angle correction, use the ArcoFix x-ray template.

Place the template on a lateral x-ray showing the levels to be instrumented. Position the caudal swivel head on the caudal bony endplate so that the posterior screw hole is located close to the cortical bone. Slide the cranial swivel head onto the cranial bony endplate and choose the appropriate implant size.

Note: Template images are 115% of actual implant size to correspond to typical radiographic magnification.



Insert ArcoFix

General note on sequence of surgical steps

Expose the pathology and perform the corpectomy. Insert an ArcoFix implant and perform the reduction. With the ArcoFix already in place insert a vertebral body replacement or bone graft through the same incision.

If the anatomical access area is restricted by a narrow anatomical situation, or an atypical vascular situation is present, the bone graft or vertebral body replacement can be inserted before the fixation system is in place.

1

Position patient

A lateral approach from the left is recommended, as the aorta is easier to mobilize than the inferior vena cava.

Place the patient in a right lateral decubitus position with the left arm comfortably stabilized. The posterior wall of the vertebrae must be oriented parallel to the beam of the image intensifier.

Important: Confirm that the patient is not placed in a scoliotic position and that the spine is straight in AP view.

2
Perform corpectomy

After exposing the affected level, perform the corpectomy and check for canal clearance.

3
Select implant size

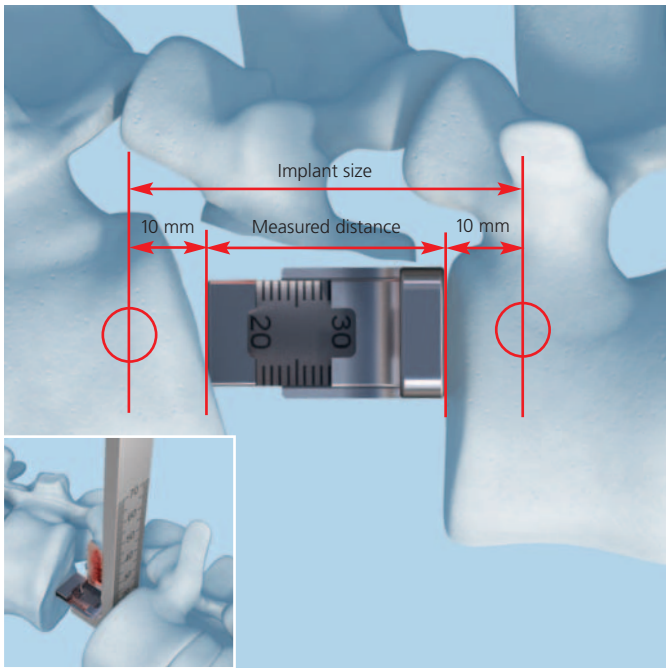
Instrument	
03.661.010	Metal Tape Gauge, measuring range 20 to 150 mm

Using the metal tape gauge, measure the distance between the cranial and caudal endplate adjacent to the defect.

Add 20 mm to the measured distance and select the implant size that covers the necessary expansion range.

Measured distance + 20 mm = implant size

Note: The expansion range of the implants refers to the distance between the two posteriorly located screws.



4
Prepare implant

Instruments	
68.661.012.02	Insert, size ¼, for ArcoFix-PF Screws, for No. 68.661.002
03.661.003	Screwdriver Shaft Stardrive 3.5 mm, spherical, T25
388.654	Ratchet with Handle, with Hexagonal Quick Coupling ∅ 6.0 mm
03.661.017	Drill Sleeve for Fixation Pin for temporary use

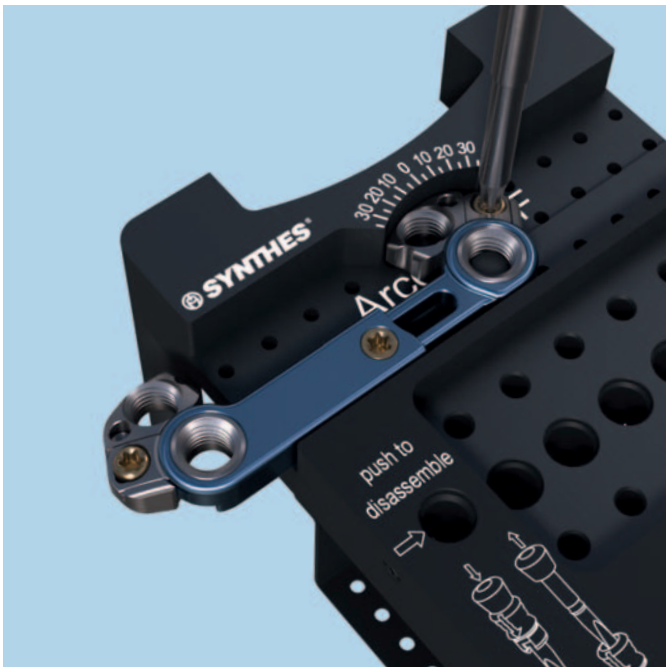
Place the implant onto the assembly block in the ArcoFix screw insert.

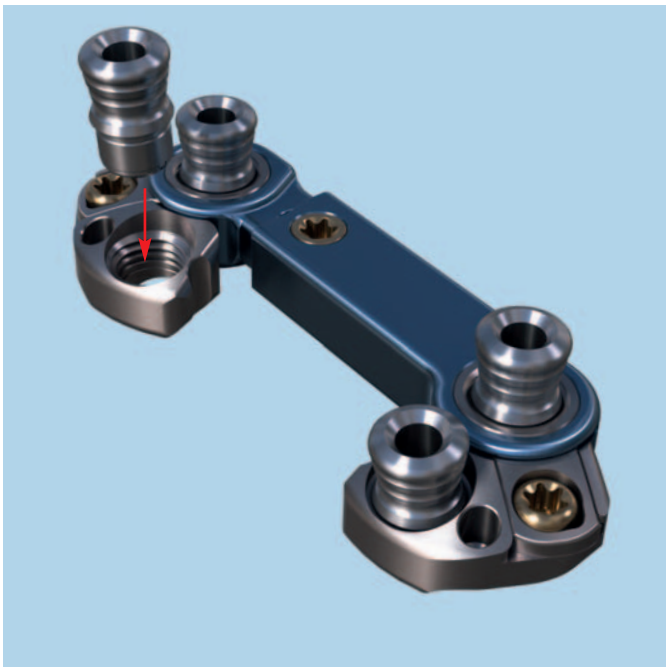
Orient each swivel head individually at the angle required so that the vertebral body screws are aligned parallel to the endplates. Finger-tighten both angle-locking screws. Leave the height adjustment feature unlocked so that the implant height can be intraoperatively adapted to the anatomy.

Note: The height-locking screw and angle-locking screws can be unlocked at any time to allow adjustment of implant height and/or swivel-plate angle.

Insert a drill sleeve into each screw hole.

Warning: For any preliminary locking (or unlocking) of any gold locking screws only finger tightening (or finger untightening) is allowed.
Do not turn the screw beyond the stop.





5
Position implant

Instrument

03.661.011	Holding Forceps

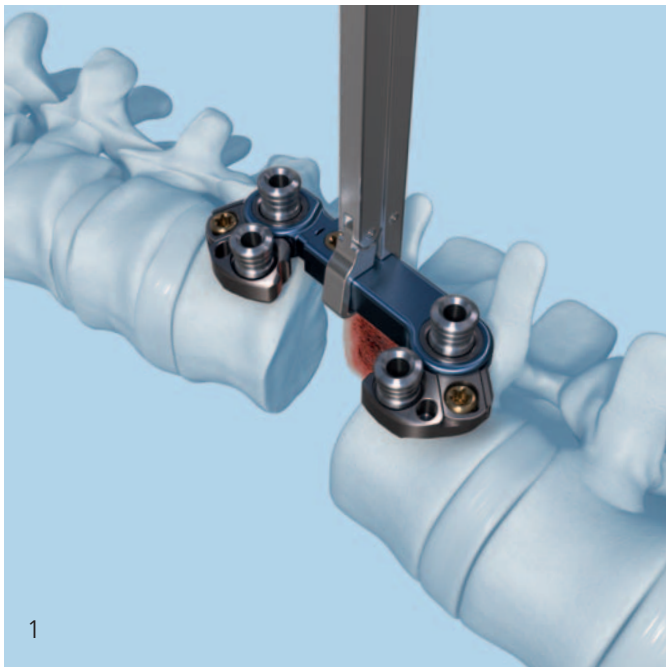
Use the holding forceps to position the implant as far posterior as possible and parallel to the posterior wall of the vertebral body. Ensure that the implant does not overlap the posterior wall of the vertebral body. (1)

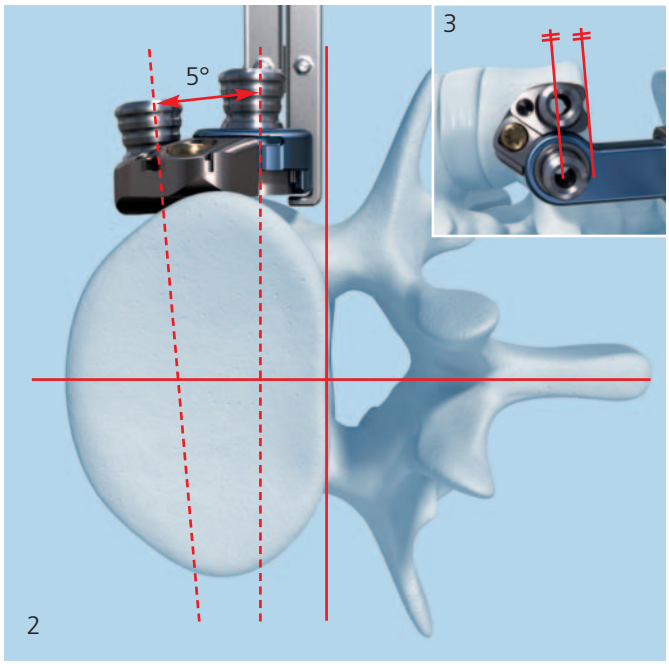
In the sagittal plane the plate has to be positioned parallel and adjacent to the lateral wall of the vertebral body to allow the posterior screws to be inserted orthogonally to the plate and parallel to the posterior wall of the vertebral body. (2)

Note: When holding the implant with the holding forceps, the instrument shaft is always oriented orthogonally to the implant surface to allow easier implant orientation in the sagittal plane.

The two swivel heads should be oriented to align the vertebral body screws parallel to the endplates (3).

Warning: The anterior screw holes have a 5° convergence to improve anchorage in the bone. Confirm that the orientation is correct when inserting the pins and screws, to avoid cross-threading.


1



6
Temporarily fix implant

Instruments	
388.654	Ratchet with Handle, with Hexagonal Quick Coupling ∅ 6.0 mm
03.661.003	Screwdriver Shaft Stardrive 3.5 mm, spherical, T25
03.661.004	Holding Sleeve for No. 03.661.003 and No 03.661.002
03.661.016	Fixation Pin for temporary use, with thread

Connect the ratchet with handle to the screwdriver shaft and insert the shaft into the holding sleeve.

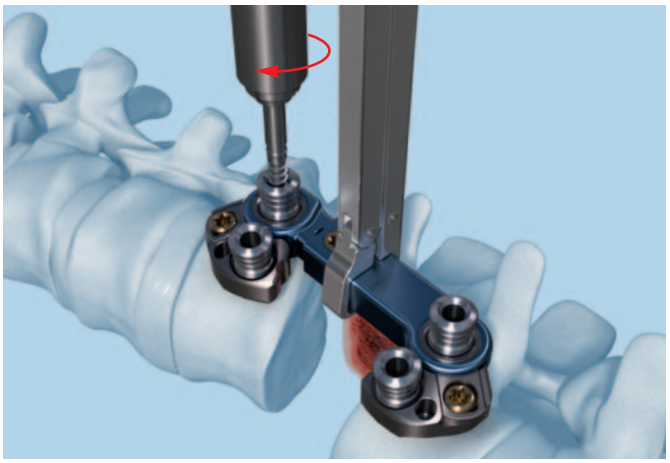
Insert a fixation pin through the cranial posterior drill sleeve, keeping the screwdriver shaft parallel to the holding forceps. The fixation pin lags the plate to the bone and prevents the implant from moving.

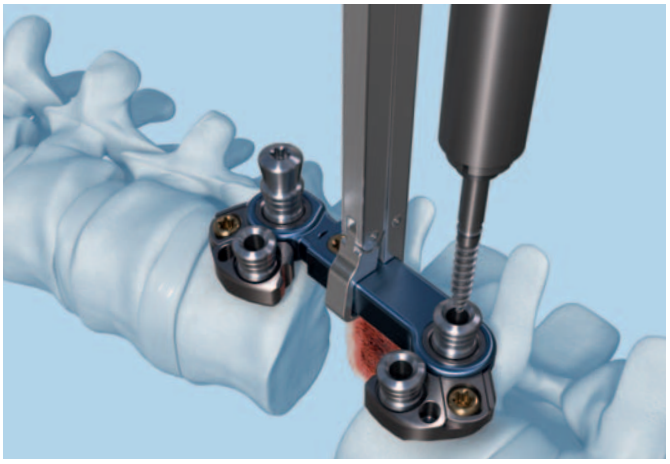
Disengage the holding sleeve and remove the screwdriver shaft, leaving the fixation pin in place.

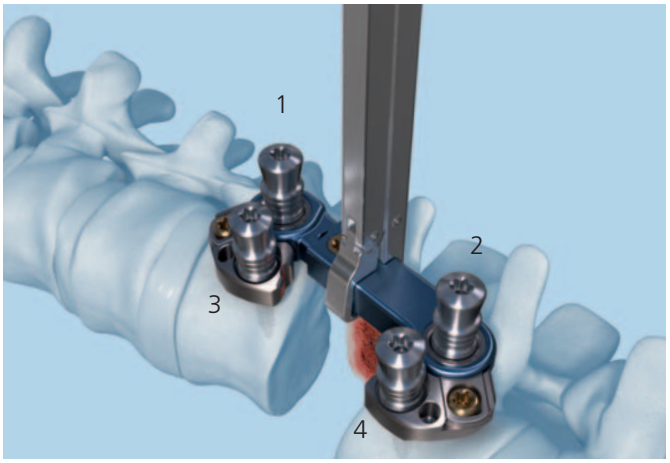
Adapt the implant length by shifting the holding forceps and insert a fixation pin through the caudal posterior drill sleeve.

Note: Maximum penetration depth of the fixation pin inserted through the drill sleeve is 20 mm.

Insert fixation pins in the remaining caudal and cranial drill sleeves following the numbering as indicated.







Alternative instrument

03.661.001	Awl ∅ 4.3 mm

Instead of the fixation pins, the awl can be used for screw hole preparation.

Check the final implant position with an image intensifier. It should lie as flush as possible on the vertebral body and oriented in the sagittal plane as described in step 5.

7
Determine screw length

Instruments	
03.661.003	Screwdriver Shaft Stardrive 3.5 mm, spherical, T25
03.661.004	Holding Sleeve for No. 03.661.003 and No 03.661.002
388.654	Ratchet with Handle, with Hexagonal Quick Coupling ∅ 6.0 mm
319.011	Depth Gauge, measuring range to 110 mm

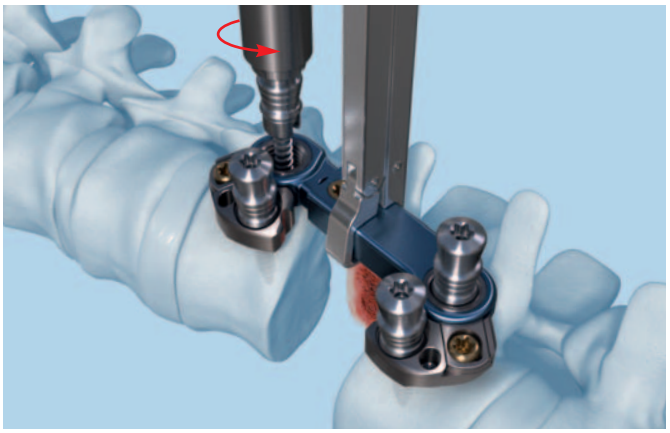
Remove the cranial posterior fixation pin with the holding sleeve engaged. The drill sleeve will be removed simultaneously.

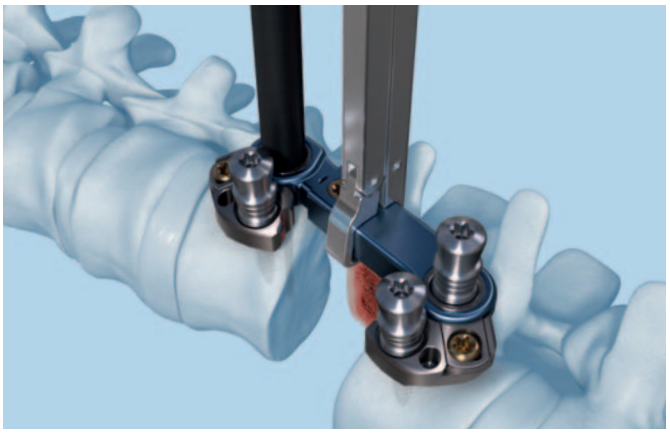
Determine the appropriate screw length with the help of the depth gauge, or based on previously taken x-rays and CT scans.

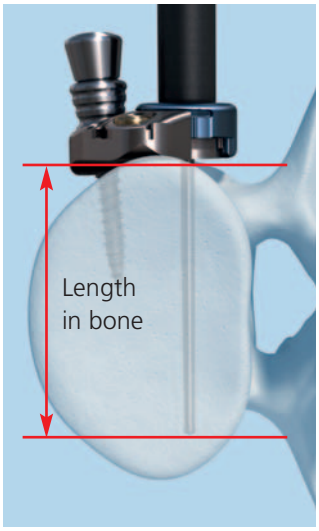
Subtract 7 mm from the measurement on the depth gauge, to obtain the maximal screw length. Take the next shorter screw size to get optimal screw purchase without perforating the distal cortex.

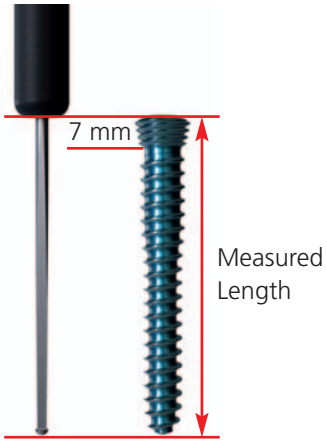
Measured length – 7 mm = maximal screw length

Notes
- Screws should have maximum bone purchase in the vertebral body without perforating the distal cortex.
- The available screw lengths listed on page 29 indicate the distance from the first thread to the tip of the screw. (length in bone)









8
Insert first vertebral body screw

Instruments	
388.654	Ratchet with handle, with Hexagonal Quick Coupling ∅ 6.0 mm
03.661.003	Screwdriver Shaft Stardrive 3.5 mm, spherical, T25
03.661.004	Holding Sleeve for No. 03.661.003 and No 03.661.002

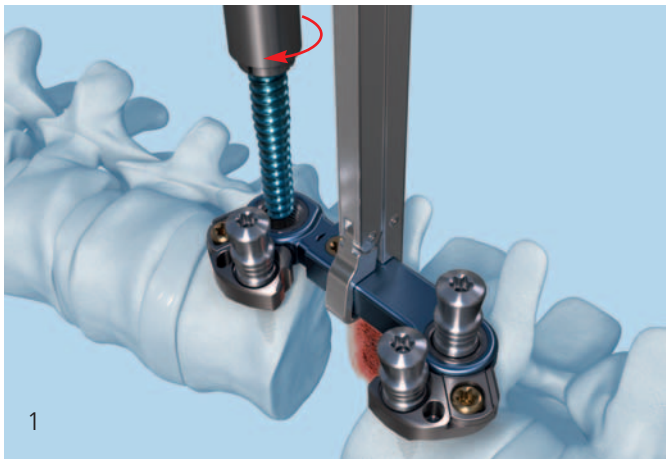
Pick up a vertebral body screw of the appropriate length and insert it into the cranial posterior screw hole. The screw will follow the pathway prepared by the fixation pin.

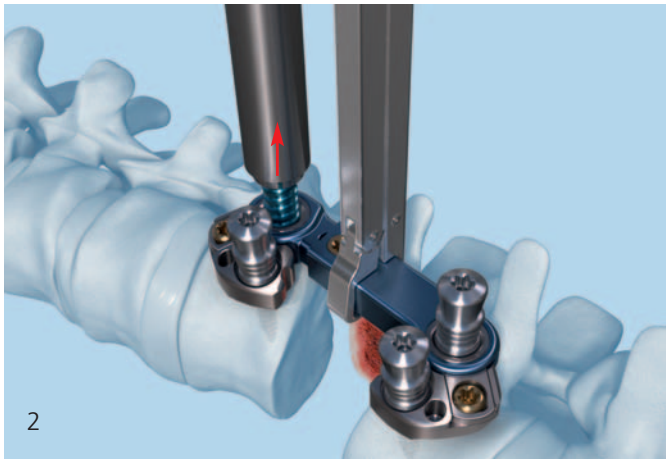
Insert the screw up to ¾ of its length. (1)

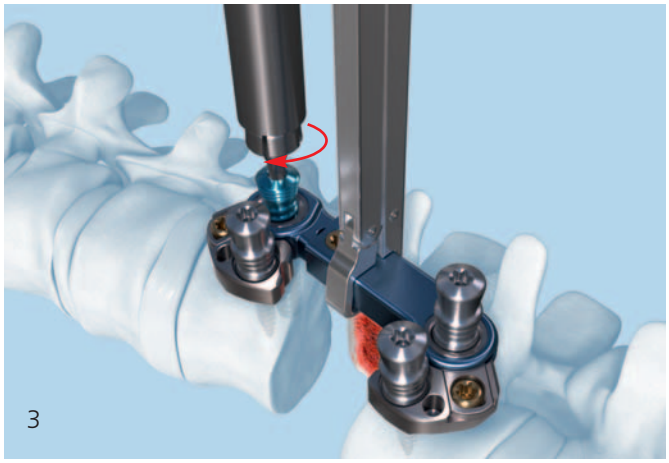
Pull the holding sleeve back. (2)

Continue insertion until the screw head is fully seated in the screw hole and hand-tightened. (3)

Note: Use the holding forceps to apply counter-torque.





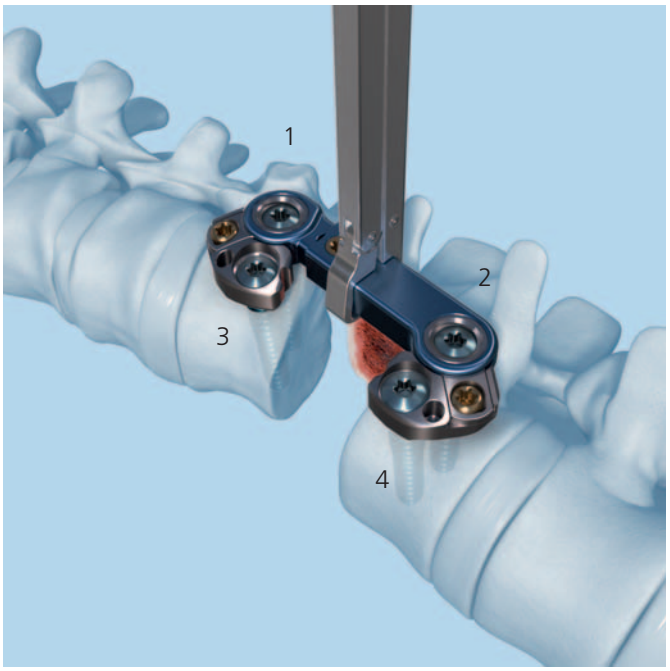


9

Insert remaining vertebral body screws

Instruments	
03.661.003	Screwdriver Shaft Stardrive 3.5 mm, spherical, T25
03.661.004	Holding Sleeve for No. 03.661.003 and No 03.661.002
388.654	Ratchet with handle, with Hexagonal Quick Coupling ∅ 6.0 mm

In the order indicated, repeat steps 7 and 8 for the remaining screws.



Alternative: Perforated augmentable screws

In case of poor bone quality or mild osteoporosis, perforated augmentable screws can be used.

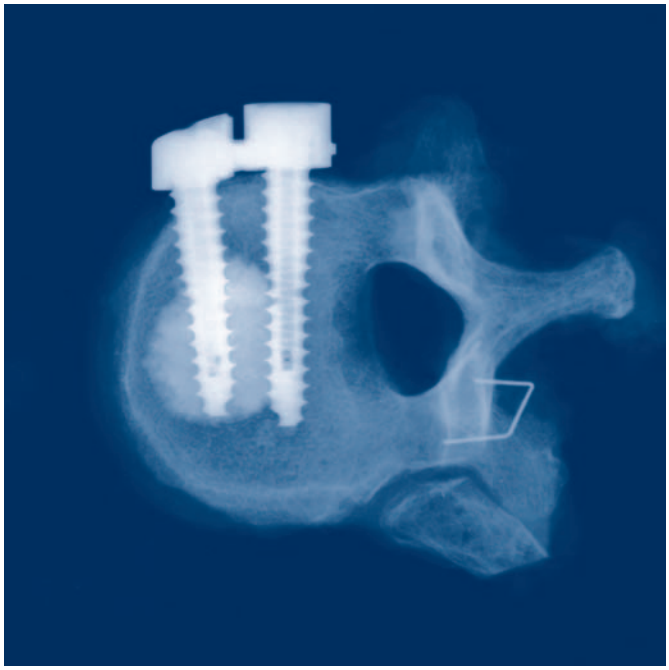
A high viscosity bone cement like Vertecem can be injected through these screws into the vertebral body to increase the resistance to cut-through.

Make sure the cement cannula is well inserted into the head of the perforated screw.

Please refer to the Vertecem Technique Guide (036.000.557) for further information.

Note: The use of perforated augmentable screws is recommended for the anterior screws due to the increased forces applied during the reduction maneuver.

Important: For safety reasons and in order to learn about the specific Vertecem properties, correct injection technique is instructed a special Vertecem Symposium. Prior to first Vertecem surgery, the participation to such a training by the surgeon is mandatory.



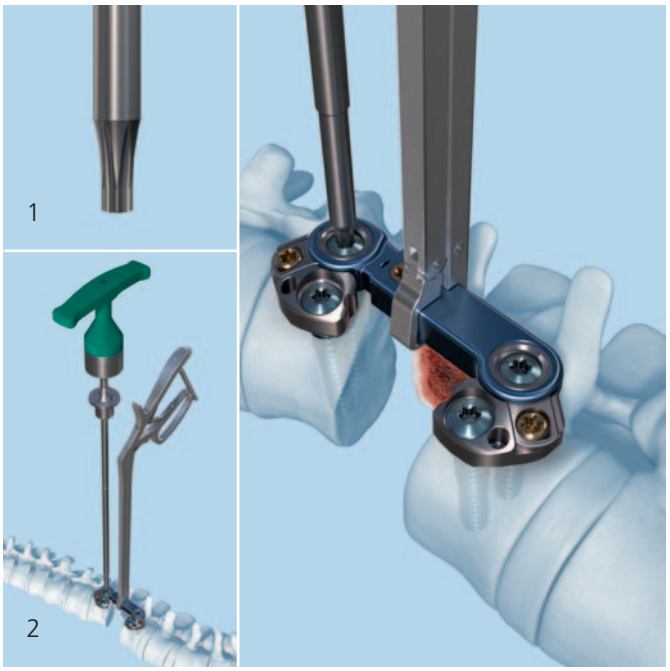
10
Tighten vertebral body screws

Instruments	
03.661.002	Screwdriver Shaft, Stardrive, T25, straight
321.133	Torque-limiting T-Handle, 7 Nm

Connect the torque-limiting T-handle to the straight screwdriver shaft (1) for final tightening of all vertebral body screws. Turn the screw until the torque limiting handle clicks.

The audible click signals that the necessary torque of 7 Nm has been reached.

Note: Use the holding forceps to apply counter-torque. (2) The torque-limiting T-handle 7 Nm (321.133) must be serviced regularly.



11

Disengage drill sleeve from temporary fixation pins

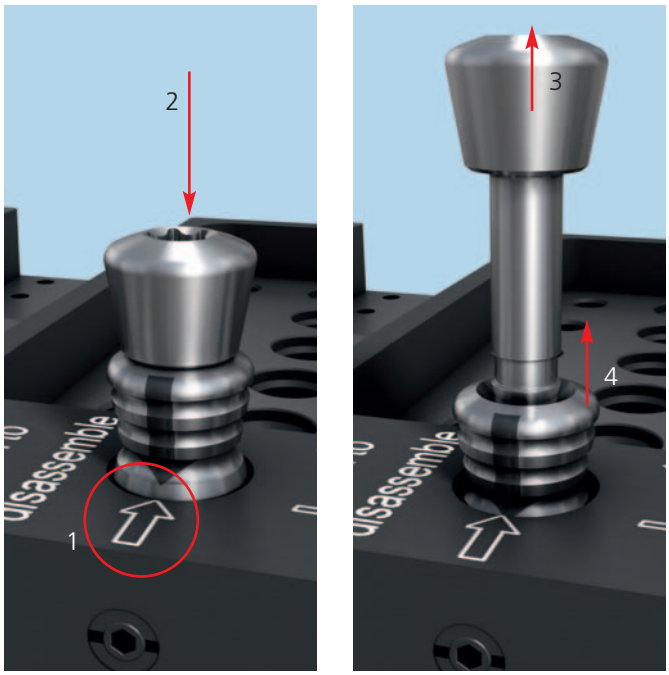
Set	
68.661.012.02	Insert, size ¼, for ArcoFix-PF Screws, for No. 68.661.002

1. Insert the engaged parts into the release tool included in the insert. Ensure that the arrow on the drill sleeve and the arrow on the insert point toward each other.

2. Push down the engaged parts.

3. Pull out the temporary fixation pin.

4. Remove the drill guide from the release tool.



Perform Reduction

Reduction concept

Instrument	
03.661.005	Reduction Instrument

The reduction instrument allows angular correction and restoration of vertebral body height, for realignment of the natural anatomy of the spine.

Manipulation options

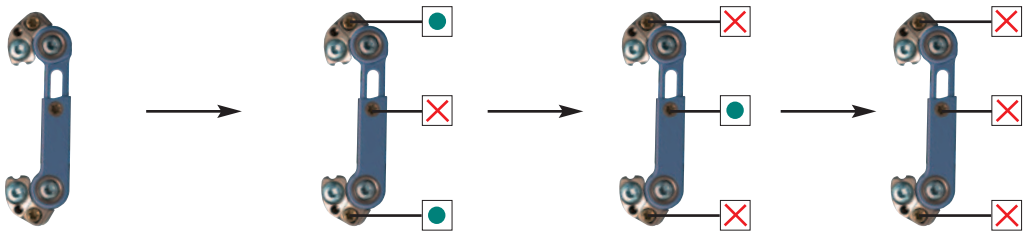
The instrument offers multiple manipulation options to support controlled reduction of the fracture.

The angle of lordosis or kyphosis can be corrected by changing the angulation of the implant's cranial and caudal swivel heads. Height can be corrected with the implant's central sliding mechanism. The swivel heads and sliding mechanism are individually locked or unlocked with the locking screws to perform the different maneuvers.

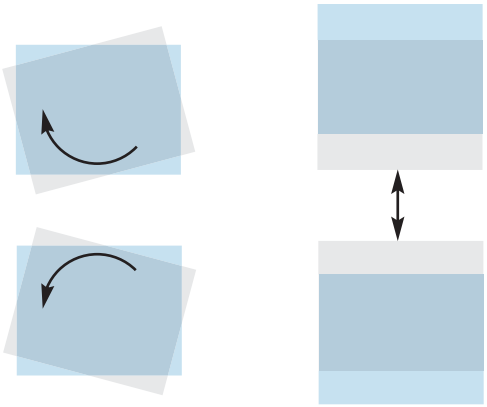
Warning: During the reduction maneuver increased forces are applied to the anterior screws. This combined with poor bone quality and high reduction forces may cause cut-through. Only apply two-finger-force on the instrument or use perforated screws filled with cement.

Step-by-step reduction

Screw setting

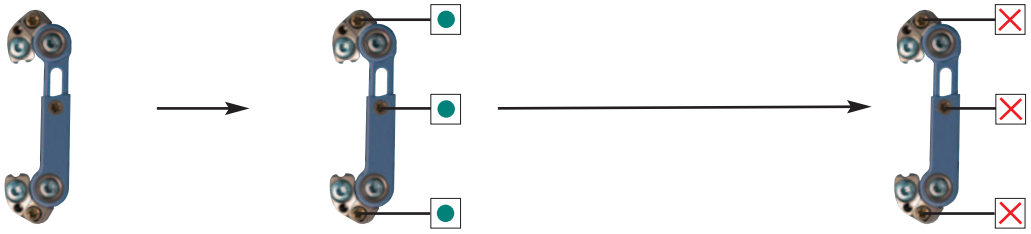


Manipulation

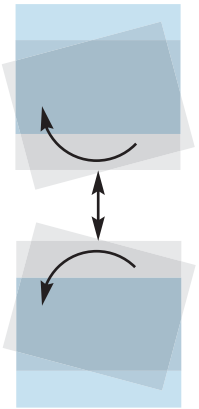


All-in-one reduction

Screw setting



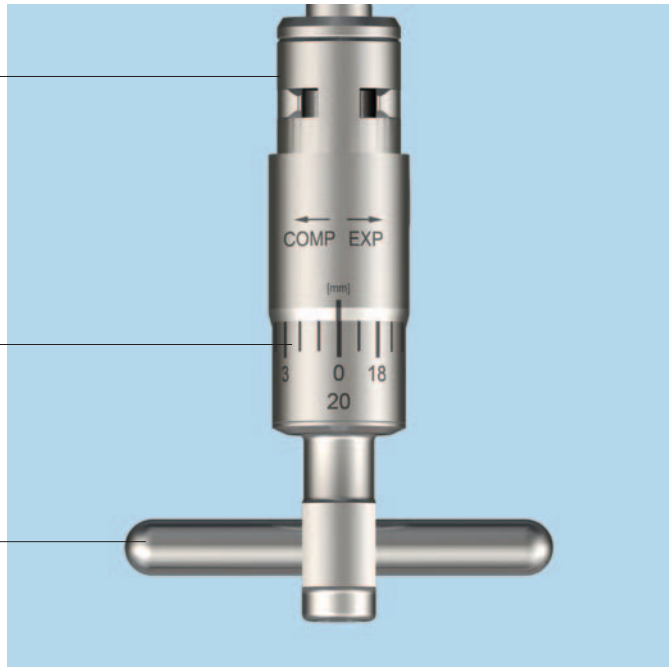
Manipulation



Warning: For any preliminary locking (or unlocking) of any gold locking screws only finger tightening (or finger untightening) is allowed.
Do not turn the screw beyond the stop.

unlocked locked

Reduction Instrument Use



Locking slider
Provides easy instrument disassembly.

Scale
Documents the effected distraction/compression pathway.

T-Handle
For distracting or compressing the toothed racks.

Direction of rotation	Action
clockwise	extension of the toothed rack
counterclockwise	retraction of the toothed rack

When activated, a ratchet in the reduction instrument allows controlled, step-by-step reduction.

Position of the lever	Result
Expansion ("E")	extension of the toothed rack possible
Neutral	unlocked
Compression ("C")	only retraction of the toothed rack possible

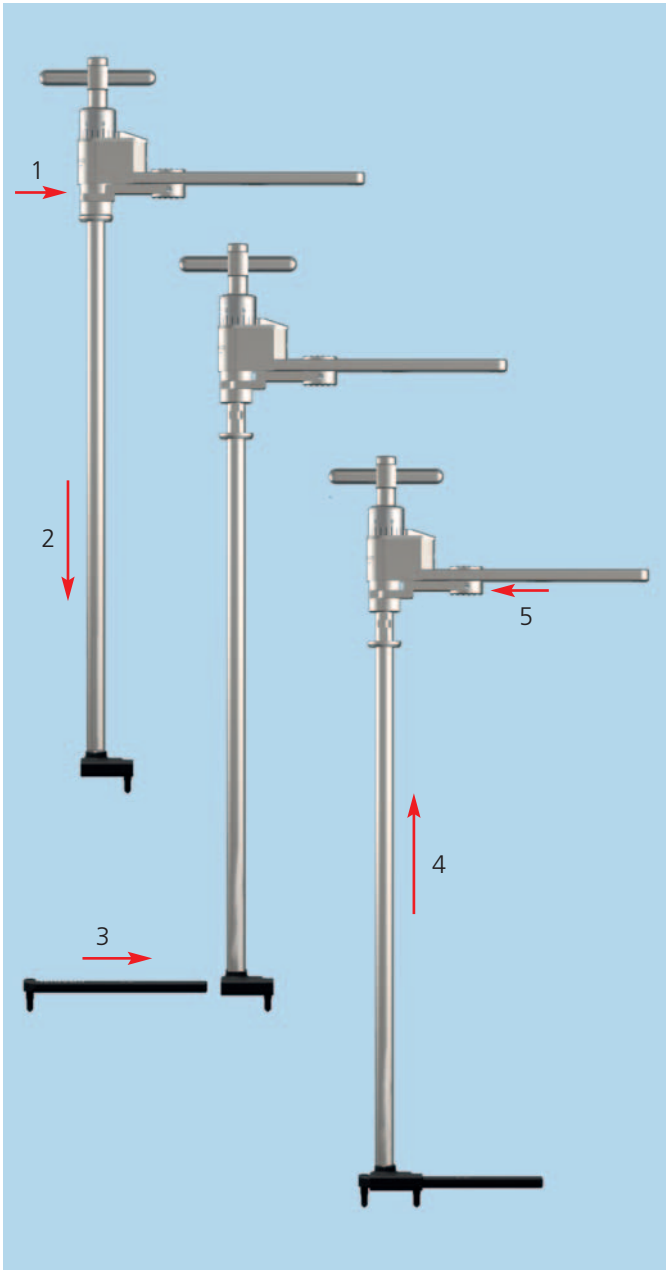
1
Select and assemble toothed rack

Instruments	
03.661.005	Reduction Instrument
03.661.006	Toothed Rack, short
03.661.007	Toothed Rack, medium
03.661.008	Toothed Rack, long
03.661.009	Toothed Rack, extra-long

Select the toothed rack that corresponds to the implant size:

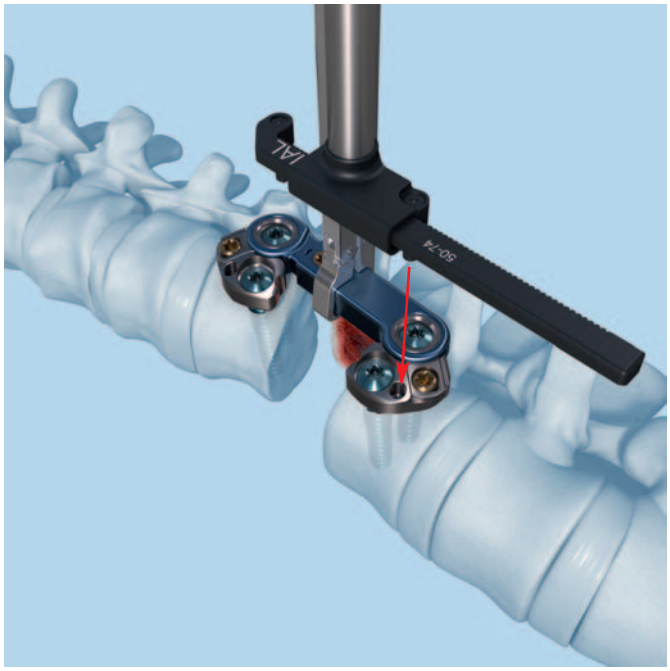
Toothed rack	Extension	For implant sizes
03.661.006	27.5 mm – 84 mm	30–34 32–38 35–44 40–54
03.661.007	27.5 mm – 104 mm	50–74
03.661.008	27.5 mm – 129 mm	69–99
03.661.009	27.5 mm – 154 mm	94–124

Lift the locking slider up (1) and push the tube (2) forward. Insert the suitable toothed rack (3), push the tube back again (4) and secure them with the locking slider (5).



2
Connect reduction instrument to implant

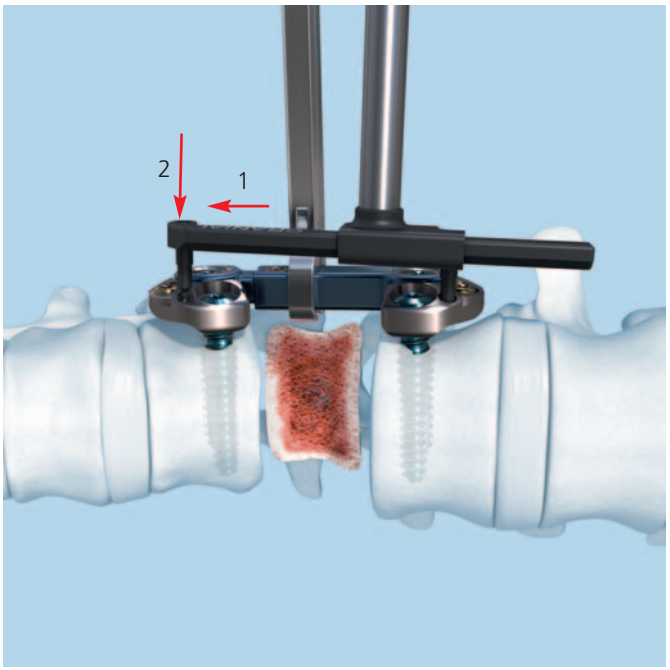
Instruments	
03.661.003	Screwdriver Shaft Stardrive 3.5 mm, spherical, T25
03.661.005	Reduction Instrument
03.661.006	Toothed Rack, short
03.661.007	Toothed Rack, medium
03.661.008	Toothed Rack, long
03.661.009	Toothed Rack, extra-long
388.654	Ratchet with Handle, with Hexagonal Quick Coupling ∅ 6.0 mm



Insert the reduction instrument with toothed rack assembled into the operation site. Position the instrument over the anteriorly located pin holes, parallel to the implant's sliding mechanism. Ensure that the screwdriver has full access to the locking screws.

Insert the fixed pin of the instrument into the pin hole of the caudal swivel head with the toothed rack pointing to the cranial swivel head.

Turn the T-handle clockwise to extend the toothed rack cranially (1) until the pin can be inserted into the pin hole of the cranial swivel head (2).



Note: The reduction instrument can be slightly tilted to ease pin insertion.

When both pins are fully engaged ensure the locking screws are locked or unlocked, according to the desired reduction maneuver, and start the reduction.

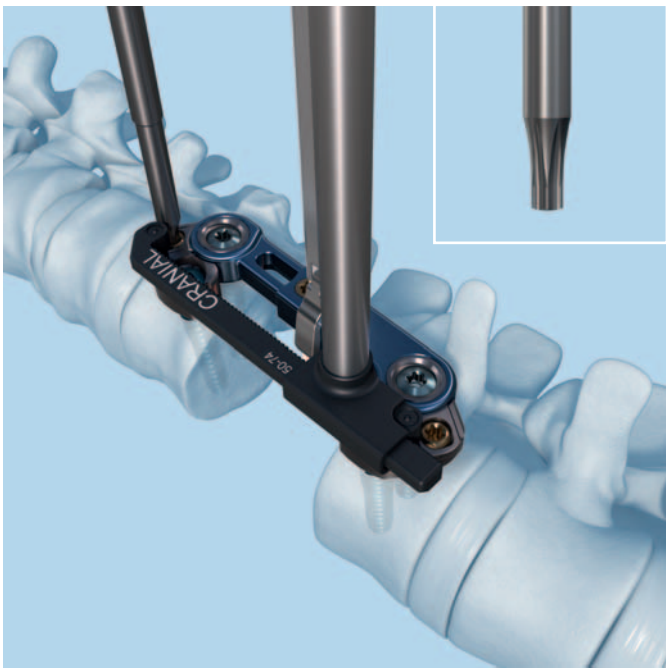
Warning: For any preliminary locking (or unlocking) of any gold locking screws only finger tightening (or finger untightening) is allowed.
Do not turn the screw beyond the stop.

3
Secure reduction

Instruments	
03.661.002	Screwdriver Shaft, Stardrive, T25, straight
321.133	Torque-limiting T-Handle, 7 Nm

Connect the torque-limiting T-handle to the straight screwdriver shaft for final tightening of all locking screws. Turn the screw until the Torque-limiting T-handle clicks.

The audible click signals that the necessary torque of 7 Nm has been reached.

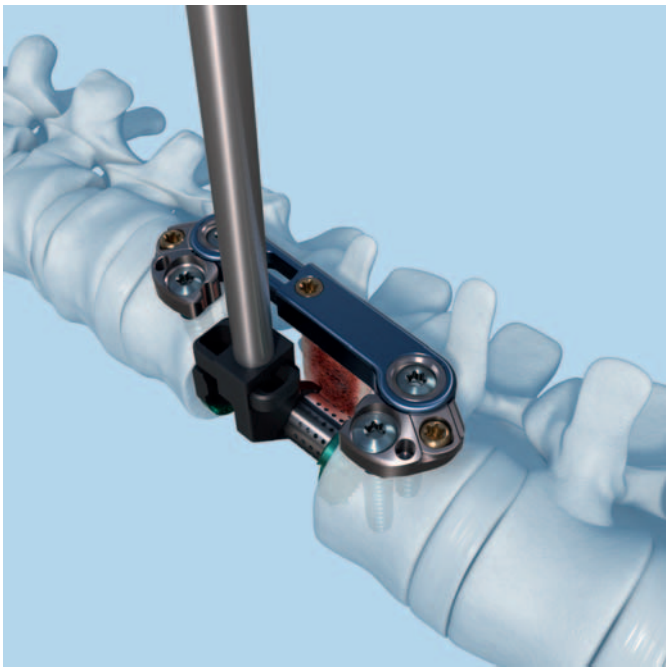


Notes:
- Use the holding forceps to apply counter-torque.
- The torque-limiting T-handle 7 Nm (321.133) must be serviced regularly.

Insert Synex II

1
Insert implant

Instruments	
01.808.100	Set Synex II
03.807.105	Angled Spreader Top, right, distraction width 5 mm, for No. 03.807.000
03.807.108	Angled Spreader Top, right, distraction width 8 mm, for No. 03.807.000
03.807.115	Angled Spreader Top, right, distraction width 15 mm, for No. 03.807.000
03.807.125	Angled Spreader Top, right, distraction width 26 mm, for No. 03.807.000
03.807.150	Release Tool for Angled Shaft, for No. 03.807.000
03.807.100	Angled Shaft, right, for No. 03.807.000



Different Vertebral Body Replacement devices (e.g. Synex, SynMesh) or bone graft can be used together with ArcoFix. The following steps describe the insertion of Synex II past the already inserted ArcoFix. Depending on the size of the approach this technique might be technically more demanding when inserting other Vertebral Body Replacement devices as they may not have a similar slim design and appropriate instruments.

Alternatively the VBR has to be inserted prior to the ArcoFix plate.

1. Select and assemble a Synex II implant appropriate to the reduction achieved with ArcoFix.

2. Insert the implant with the angled spreader past the already inserted ArcoFix. Expand it when the optimal position is reached. Ensure that the center body is configured for an anterior lateral left approach (see step 5 in Synex II Technique Guide).

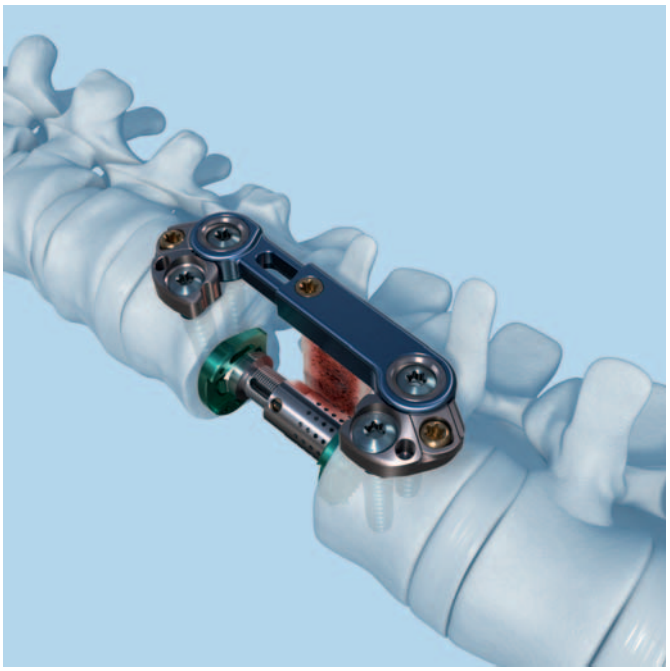
To adjust the position, push the release tool through the instrument cannulation, attach it to the angled spreader by turning it clockwise, and push it into the ring on the implant.

Refer to the Technique Guide for Synex II (036.000.904) for further information.

3. Remove the angled spreader and verify the correct position of the implant under image intensifier control.

Apply bone material to create optimal conditions for fusion. The slim central body allows sufficient space for affixing bone grafts.

Note: If the posterior edge of the vertebral body is resected, ensure that the position of the bone graft does not extend beyond the dorsal wall of the implant.



Implants

ArcoFix-PF Single-rod implants 7.0, monosegmental, Titanium Alloy (TAN), blue

Art No.	Expansion range
04.661.011	30–34 mm
04.661.012	32–38 mm
04.661.013	35–44 mm
04.661.014	40–54 mm

ArcoFix-PF Single-rod implants 7.0, bisegmental, Titanium Alloy (TAN), blue

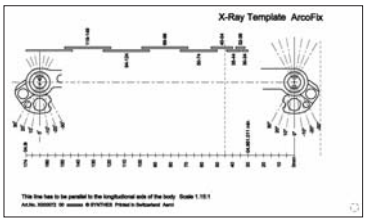
Art No.	Expansion range
04.661.015	50–74 mm
04.661.016	69–99 mm
04.661.017	94–124 mm

Vertebral Body Screw ∅ 7.0 mm, self-tapping, Titanium Alloy (TAN), light blue

Art. No.	Length
04.661.125	25 mm
04.661.130	30 mm
04.661.135	35 mm
04.661.140	40 mm
04.661.145	45 mm
04.661.150	50 mm
04.661.155	55 mm
04.661.160	60 mm

Instruments

03.661.001	Awl ∅ 4.3 mm, length 370 mm	
03.661.002	Screwdriver Shaft, Stardrive, T25, straight	
03.661.003	Screwdriver Shaft Stardrive 3.5 mm, spherical, T25	
03.661.004	Holding Sleeve for No. 03.661.003 and No. 03.661.002	
03.661.005	Reduction Instrument	
03.661.006	Toothed Rack, short, range 30–54 mm	
03.661.007	Toothed Rack, medium, range 50–74 mm	
03.661.008	Toothed Rack, long, range 69–99 mm	
03.661.009	Toothed Rack, extra-long, range 94–124 mm	

03.661.010	Metal Tape Gauge, measuring range 20 to 150 mm	
03.661.011	Holding Forceps	
03.661.016	Fixation Pin for temporary use, with thread	
03.661.017	Drill Sleeve for Fixation Pin for temporary use	
319.011	Depth Gauge for Pedicle Screws,measuring range to 110 mm	
388.654	Ratchet with Handle, with Hexagonal Quick Coupling ∅ 6.0 mm	
321.133	Torque-limiting T-handle, 7 Nm	
X000072	X-Ray Template for ArcoFix Implants	

Optional

Optional Implants

ArcoFix-PF Single-rod implants 7.0, multisegmental, Titanium Alloy (TAN), blue*

Art No.	Expansion range
04.661.018	119–149 mm
04.661.019	144–174 mm

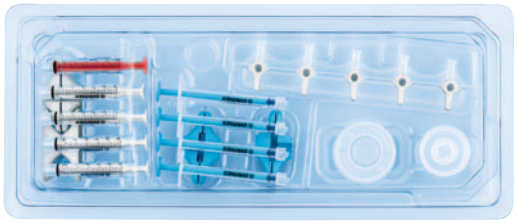
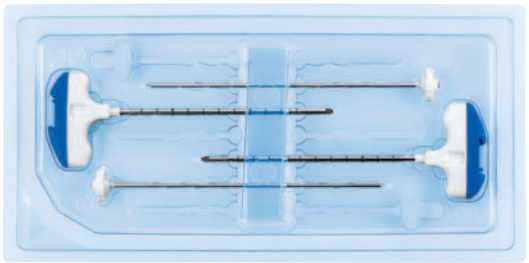
* only available on request

Optional Instruments

03.661.022	Fixation Pin for temporary use

03.661.023	Toothed Rack extra-long, range 119 to 174 mm

Screw augmentation

03.702.010	Viscosafe Viscometer	
07.702.010	Vertecem Mixing Kit	
07.702.210	Viscosafe Injection Kit	
07.702.212.02S	Screw Cementation Kit, sterile	

Vertebral Body Screw ∅ 7.0 mm, self-tapping, perforated, Titanium Alloy (TAN), purple*

Art. No.	Length
04.661.225S	25 mm
04.661.230S	30 mm
04.661.235S	35 mm
04.661.240S	40 mm
04.661.245S	45 mm
04.661.250S	50 mm
04.661.255S	55 mm
04.661.260S	60 mm

* sterile packed only

Synthes GmbH
Eimattstrasse 3
CH-4436 Oberdorf
www.synthes.com

All technique guides are available as PDF files at
www.synthes.com/lit

CE
0123

036.000.545 version AC 09/2011 50147424