

Zero profile anterior cervical interbody fusion (ACIF) device

ZERO-P®

Stand-Alone Implant

Surgical Technique



 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.depuyshnthes.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.depuyshnthes.com/hcp/reprocessing-care-maintenance>

Table of Contents

Introduction	ZERO-P® Stand-Alone Implant	2
	AO Spine Principles	4

Surgical Technique	Considerations for Use Adjacent to a Prior Fusion	5
	Patient Positioning, Exposure and Discectomy	7
	Implant Insertion	9
	Screw Fixation	
	• Option A: Aiming Device	14
	• Option B: Drill Guide and Freehand Screw	19
	• Option C: Threaded Drill Guide and Freehand Screw	22
• Option D: Awl and Freehand Screw	25	
• Option E: Angled Instruments	28	
Implant Removal	31	

Indications and Contraindications	35
--	----

Bibliography	36
---------------------	----

For Product Catalog contact your local
DePuy Synthes representative.

ZERO-P Stand-Alone Implant

Zero profile anterior cervical interbody fusion (ACIF) device.

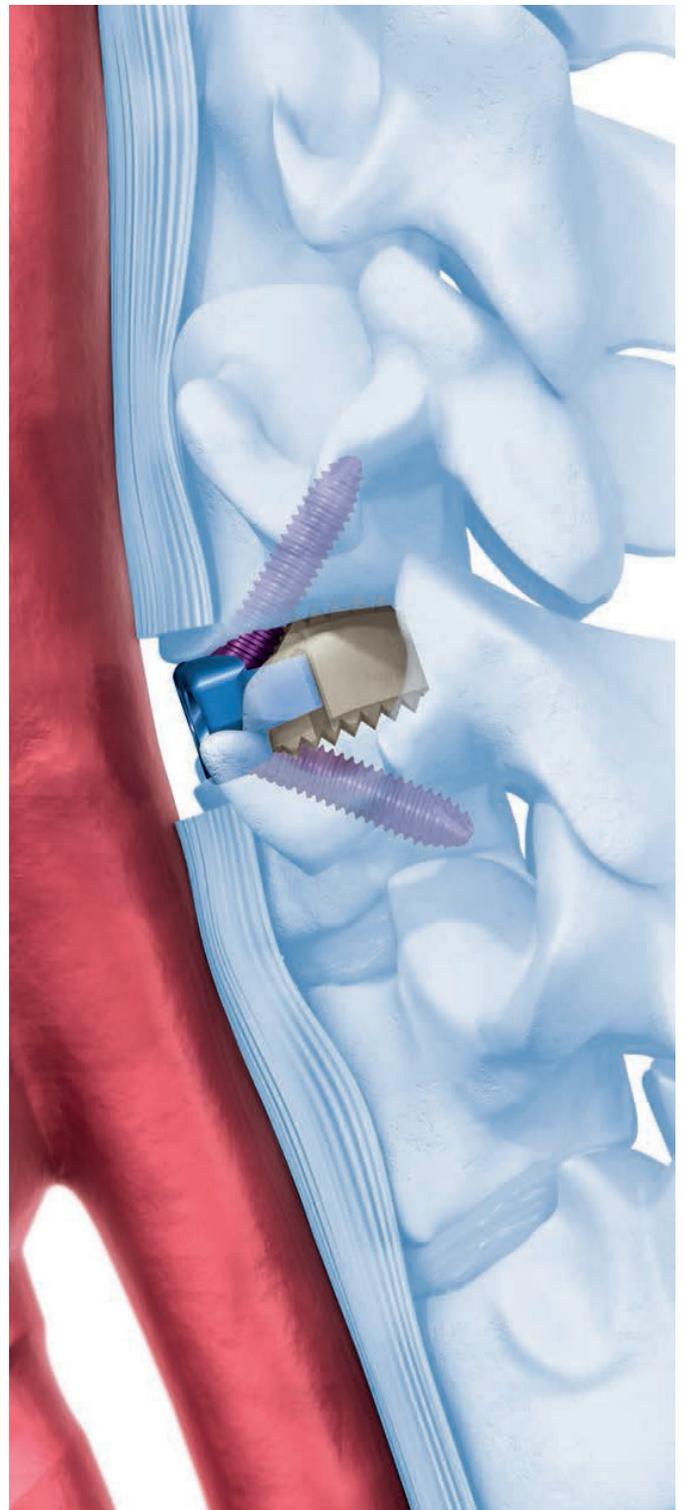
Stand-alone ACIF implant

The ZERO-P implant is a stand-alone device for use in cervical interbody fusion, designed to combine the functionality of a cervical interbody cage with an anterior cervical plate.

Zero Profile

The implant is designed to be contained within the excised disc space and does not protrude past the anterior wall of the vertebral body as do anterior cervical plates.

In addition, preparation of the anterior surface of the vertebral body is limited because the implant does not lie against this surface.

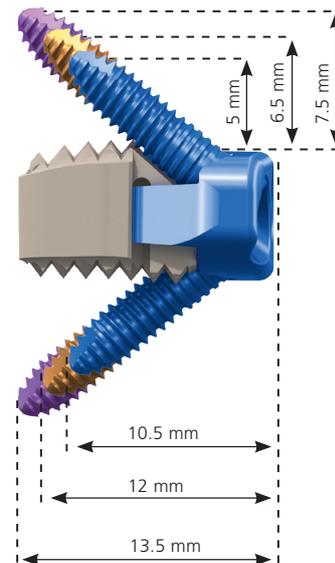
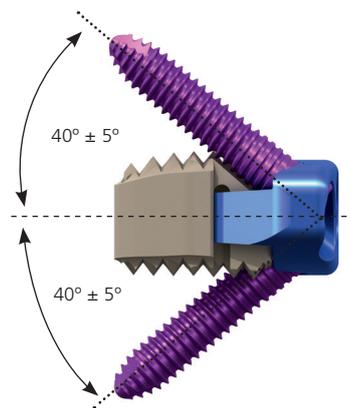
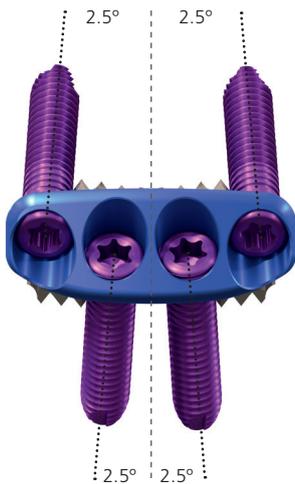
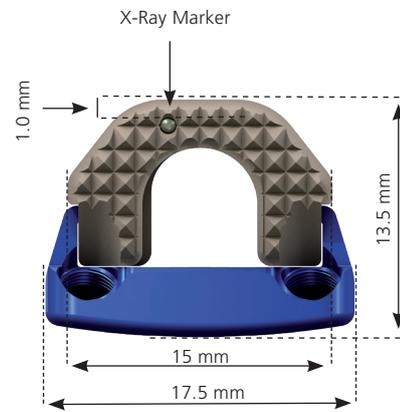


PEEK interbody cage

- Radiopaque titanium alloy marker for posterior visualization during imaging
- Cage component is made of PEEK-Optima® (Polyetheretherketone)
- Teeth on the superior and inferior implant surfaces

Titanium alloy plate and locking head screws

- Screws form a bone wedge with a $40^\circ \pm 5^\circ$ cranial/caudal angle and 2.5° medial/lateral angle
- One-step locking screws
- Self-tapping screws



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}

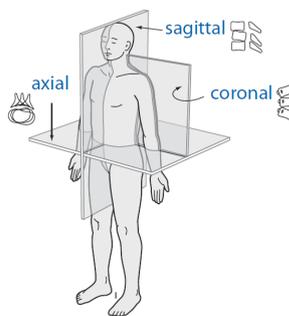
Stability

Stabilization to achieve a specific therapeutic outcome



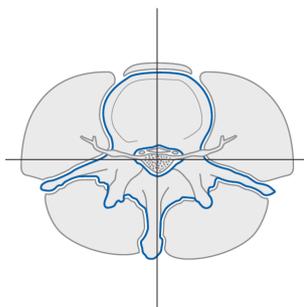
Alignment

Balancing the spine in three dimensions



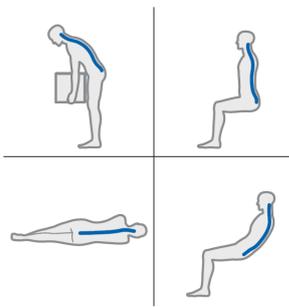
Biology

Etiology, pathogenesis, neural protection, and tissue healing



Function

Preservations and restoration of function to prevent disability



Copyright © 2012 by AOSpine

Considerations for Use Adjacent to a Prior Fusion

When implanting ZERO-P adjacent to a prior fusion, take care to avoid placing the ZERO-P cage and screws in direct contact with previously implanted hardware. As necessary, remove adjacent-level hardware that prevents Zero-P from being implanted using the correct technique.

Precaution: Placement of ZERO-P adjacent to a previous, multi-level fusion could result in increased loading on the screws. Additional posterior supplemental fixation should be considered in cases where ZERO-P is placed adjacent to a previous, multi-level fusion.

Do not place ZERO-P adjacent to previously implanted hardware if the adjacent level cannot be confirmed to be fused or where fusion has not occurred.

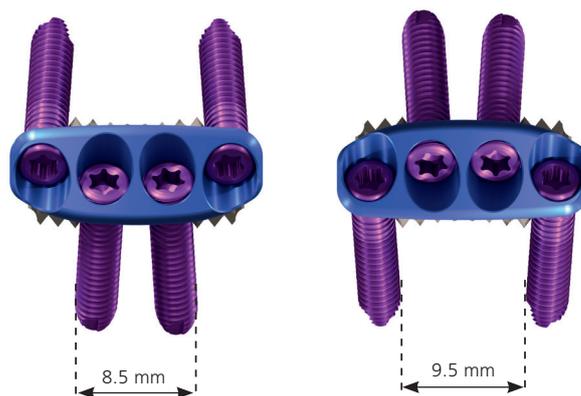
- ⓘ **Warning:** Use radiographic imaging to verify final implant position relative to the vertebral bodies in the AP and lateral direction and remaining implanted hardware associated with the previously fused level.

To accommodate previously placed hardware, orient the ZERO-P implants with lordotic and parallel sagittal profiles with either the medial screws facing cranially or caudally. Consider screw dimensions to determine desired orientation.

Precaution: Do not orient ZERO-P implants having convex sagittal profiles with medial screws facing cranial. Orienting convex sagittal profile implants with medial screws facing cranial may prevent proper seating of the implant between vertebral bodies.

Warnings:

- If adjacent hardware prevents all four screws from being implanted, a different device should be used, as increased loading may be placed on the screws leading to potential post-operative device failure and potentially increased harm to the patient.
- If any screw cannot be inserted at the correct trajectory or locked to the plate according to recommended techniques as described in steps A1-E4, a different device should be used to avoid the potential risk of screw back-out or screw failure.



Warnings continued on next page.

- **Confirm that the ZERO-P implant is not placed in direct contact with implanted hardware associated with the previously fused level. If the ZERO-P implant remains in direct contact with hardware associated with the previously fused level, increased loading may be placed on the ZERO-P implant leading to potential post-operative device failure and potential harm to the patient.**

Patient Positioning, Exposure and Discectomy

1. Patient Positioning

Using the standard surgical approach, expose the vertebral bodies to be fused. Prepare the fusion site following the appropriate technique for the given indication.

Position the patient in a supine position on a radiolucent operating table. Ensure that the neck of the patient is in a sagittally neutral position and supported by a cushion. When treating C6 – C7 make sure that the shoulders do not limit the x-ray monitoring.

- For all cases, both vertebrae should be completely visible on radiographic imaging.



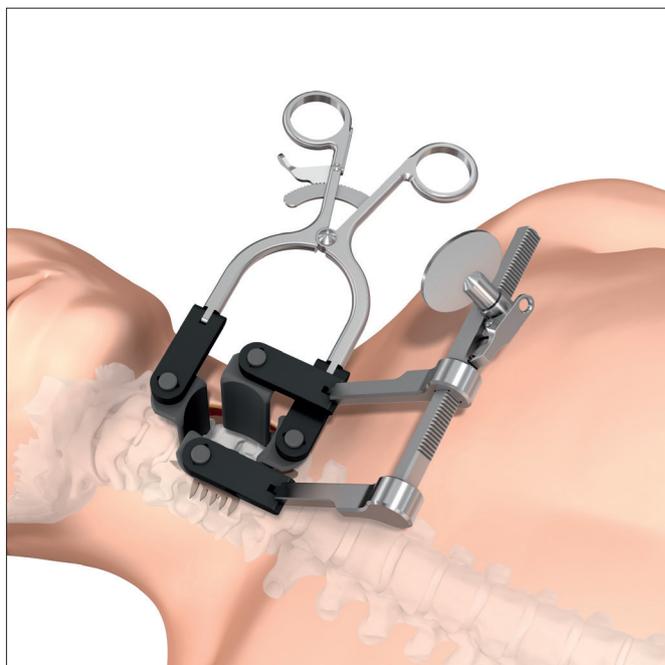
2. Access

Optional set

187.797	Cervical Retractors and Distractors
---------	-------------------------------------

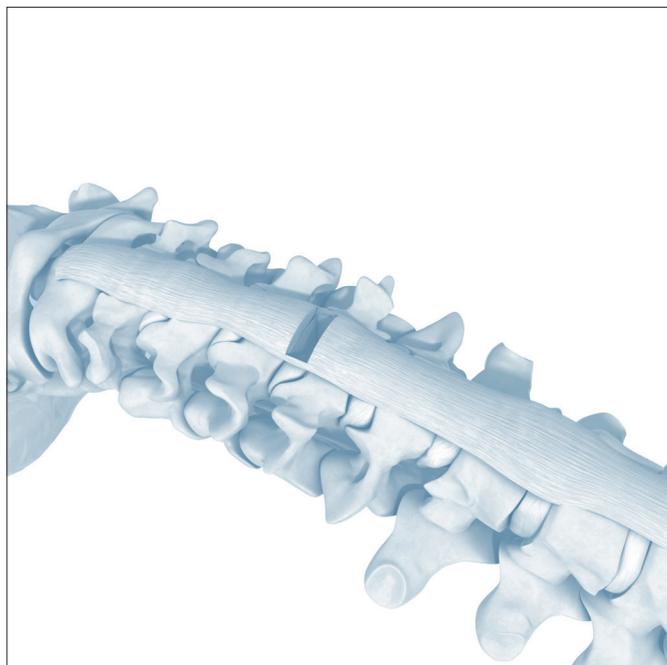
- Locate the correct operative level using radiographic imaging.
Expose the intervertebral disc and the adjacent vertebral bodies through a standard anterior approach to the cervical spine.

Precaution: Careful positioning of the retractor is required to protect against soft tissue damage.



3. Discectomy

Prepare the fusion site following the appropriate technique for the given indication.



Optional set

187.797 Cervical Retractors and Distractors

Perform segmental distraction.

Note: Distraction of the segment is essential for restoring disc height and for providing access to the intervertebral space.



Implant Insertion

1. Determine appropriate implant

Instruments

03.617.720–729	Zero-P Trial Spacer, parallel, heights 5–12 mm, purple
03.617.750–759	Zero-P Trial Spacer, lordotic, heights 5–12 mm, blue
03.617.780–789	Zero-P Trial Spacer, convex, heights 5–12 mm, gold
03.617.730–739	Zero-P Trial Spacer, large, parallel, heights 5–12 mm, purple
03.617.760–769	Zero-P Trial Spacer, large, lordotic, heights 5–12 mm, blue
03.617.790–799	Zero-P Trial Spacer, large, convex, heights 5–12 mm, gold

Optional instruments

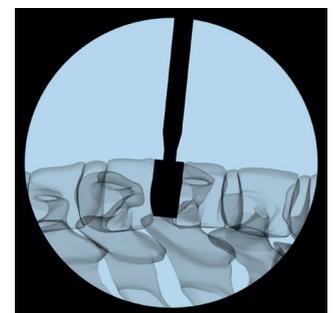
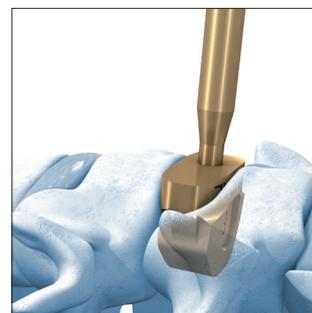
03.617.940	Handle with Large Quick Coupling
03.820.113	Mallet

Selection of the trial spacer depends on the height and depth of the intervertebral space, the preparation technique and the patient's anatomy. Choose a parallel, lordotic or convex trial spacer of the appropriate height and depth.

Position the trial spacer in the correct cranial/caudal alignment and carefully insert it into the disc space.

The mallet can be used to help insert and/or remove the trial spacer.

If preferred, a larger handle can be attached to the trial spacer.



- **Precaution:** The trial spacers do not have a depth limiter; an image intensifier should be used to check the position during insertion. With the segment fully distracted, the trial spacer should fit tightly between the end plates. Choose the appropriate implant footprint and size to accommodate variations in patient anatomy; failure to do so may injure the patient.

Notes:

- The trial spacers are color-coded by shape.
- The height of the trial spacer is 0.8 mm less than that of the corresponding implant to account for penetration of the teeth into the vertebral end plate.
- Trial spacers are not for implantation and must be removed before insertion of the ZERO-P implant.

Warning: To minimize potential risk to the patient, it is recommended to use shorter height trial spacers before using taller height trial spacers, and to use standard size footprint trial spacers before using large size footprint trial spacers.

2. Pack implant with bone graft

Instruments

03.617.984	Packing Block for Zero-P
03.617.970	Cancellous Bone Impactor for Zero-P

It is recommended to pack the ZERO-P implant with bone or bone graft substitute. Place the appropriate ZERO-P implant into the packing block.

Use the cancellous bone impactor to firmly pack graft material into the implant cavity.

Notes:

- To ensure contact with the vertebral end plates it is important to fill the implant until the graft material protrudes from the lumen in the cage.
- The Bone Impactor can only be used with the standard size footprints of ZERO-P.



3. Insert implant

Instrument

03.617.963	Aiming Device for Zero-P
------------	--------------------------

Optional instruments

03.617.980	Implant Holder for Zero-P
------------	---------------------------

03.820.113	Mallet
------------	--------

03.617.981	Impactor, flat
------------	----------------

03.617.982	Impactor with pointed ball tip
------------	--------------------------------

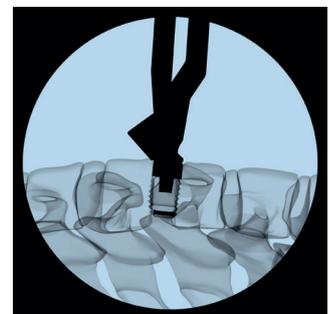
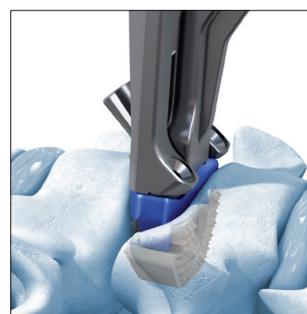
Use the aiming device or implant holder to introduce the implant into the disc space. The recommended orientation is with the medial screws pointing caudally.

- ⓘ **Precaution:** The aiming device and the implant holder do not have a depth limiter; therefore, an image intensifier should be used to check the position while inserting.

Using the aiming device

Attach the aiming device to the implant by aligning the screw holes of the implant with the retention features on the aiming device and then expanding the aiming device. Once the implant is securely attached, carefully insert the implant into the distracted segment.

If necessary, the top of the aiming device can be tapped with the mallet to advance the implant into the disc space. If distraction has been applied, release the distraction while leaving the aiming device attached to the implant.



Using the implant holder

The implant can be inserted into the disc space with the forceps-type implant holder. Once the implant is partially introduced into the disc space the implant can be advanced to the correct posterior depth using the flat impactor and/or the impactor with ball tip.

- ⓘ **Warning:** Verify final implant position relative to the vertebral bodies in the AP and lateral views using intraoperative imaging. The PEEK cage has a single posterior radiopaque marker incorporated into the implant to enable intraoperative radiographic assessment of the implant position.

Note: The recommended orientation for the implant is with the medial screws pointing caudally. For convex shaped cages this is the only orientation possible.

Screw Fixation

Option A: Aiming Device

The aiming device allows one screw to be inserted with the instrument attached to the implant. This helps to keep the implant in place while the other screw holes are prepared and screws inserted.

A1. Drill first pilot hole through drill and screw hole of aiming device

Instruments

03.617.963	Aiming Device for Zero-P
03.617.912	Drill Bit Ø 2.0 mm, drilling depth 12 mm, 3-flute, for Quick Coupling
03.617.914	Drill Bit Ø 2.0 mm, drilling depth 14 mm, 3-flute, for Quick Coupling
03.617.916	Drill Bit Ø 2.0 mm, drilling depth 16 mm, 3-flute, for Quick Coupling
03.617.903	Handle with Quick Coupling

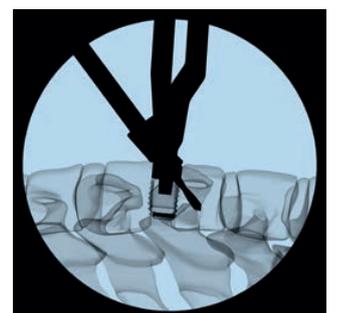
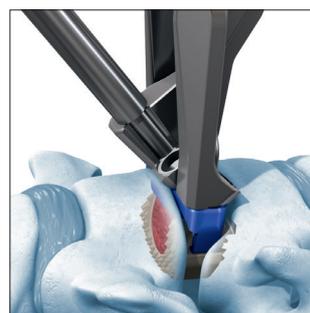
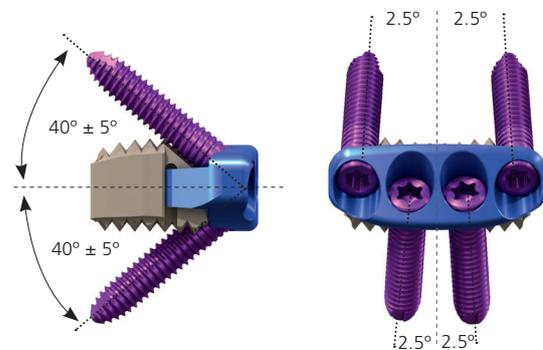
Select a drill bit of appropriate length. Insert the drill bit into the drill and screw hole of the aiming device and drill until the stop on the drill bit contacts the guide.

Warning: Intraoperative imaging should be used to verify drill position.

Remove drill bit.

Note: The drill bits are marked with a colored ring corresponding to the color-coded screw lengths.

Precaution: When using the drill bit in combination with the aiming device, take care to apply only axial forces to the drill bit. Bending forces applied when the tip of the drill bit is engaged in the aiming device can lead to the drill bit breaking.



A2. Insert first screw

Instruments

03.110.002 Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling

03.617.902 Screwdriver Shaft Stardrive, T8, self-holding

03.617.903 Handle with Quick Coupling

Optional instrument

03.617.901 Holding Sleeve for Screws for use with No. 03.617.902

03.110.005 Handle for Torque Limiters 0.4/0.8/1.2 Nm

Select the appropriate screw length according to the preoperative planning and intraoperative findings.

Assemble the torque limiter to the screwdriver shaft and handle.

Precaution: If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

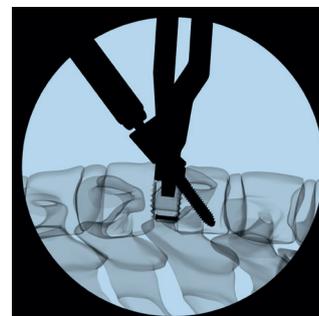
Load a screw onto the screwdriver with torque limiter. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.

Note: Retract the sleeve when inserting the first screw through the aiming device.

Advance the screw until the head of the screw contacts the plate.

ⓘ **Warning:** Intraoperative imaging should be used to verify screw position.

Precaution: The screws should be tightened only after all screws have been inserted.



A3. Drill remaining pilot holes

Instruments

03.617.963	Aiming Device for Zero-P
03.617.912	Drill Bit Ø 2.0 mm, drilling depth 12 mm, 3-flute, for Quick Coupling
03.617.914	Drill Bit Ø 2.0 mm, drilling depth 14 mm, 3-flute, for Quick Coupling
03.617.916	Drill Bit Ø 2.0 mm, drilling depth 16 mm, 3-flute, for Quick Coupling
03.617.903	Handle with Quick Coupling

Select a drill bit of appropriate length. Insert the drill bit into a drill hole of the aiming device and drill until the stop on the drill bit contacts the guide.

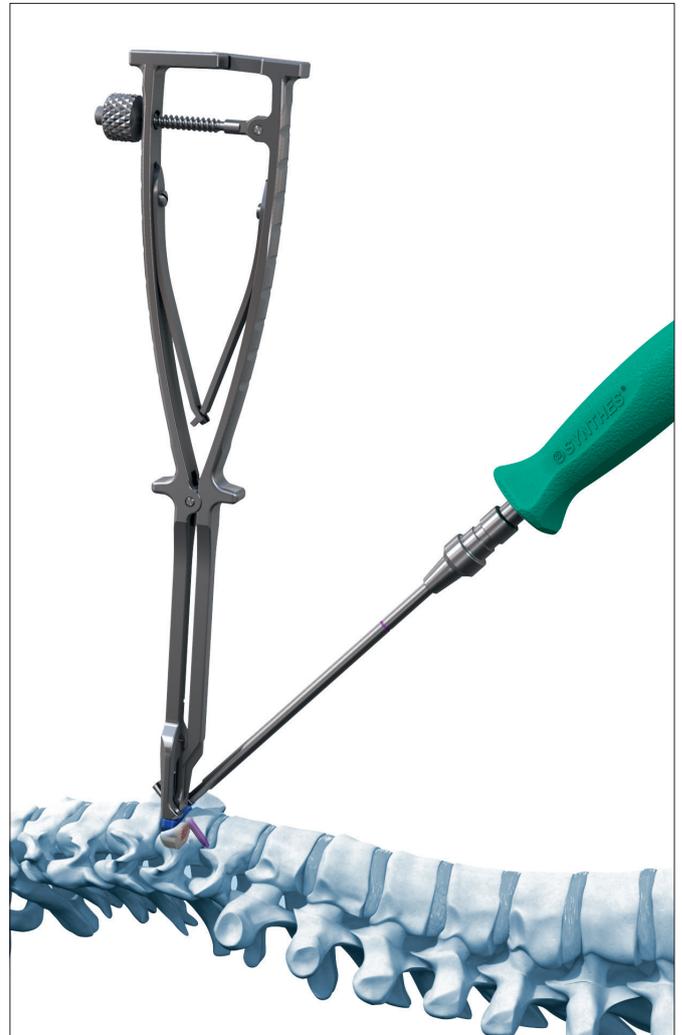
ⓘ **Warning:** Intraoperative imaging should be used to verify drill position.

Remove the drill bit.

Repeat for the remaining screw holes.

Note: The drill bits are marked with a colored ring corresponding to the color-coded screw lengths.

Precaution: When using the drill bit in combination with the aiming device, take care to apply only axial forces to the drill bit. Bending forces applied when the tip of the drill bit is engaged in the aiming device can lead to the drill bit breaking.



A4. Insert remaining screws

Instruments

03.110.002	Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling
03.617.902	Screwdriver Shaft Stardrive, T8, self-holding
03.617.903	Handle with Quick Coupling Optional instruments
03.617.901	Holding Sleeve for Screws for use with No. 03.617.902
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm

Remove the aiming device from the implant.

Load a screw onto the screwdriver with torque limiter.
The screwdriver is designed to be self-retaining.
Alternatively, the holding sleeve may also be used for
screw retention.

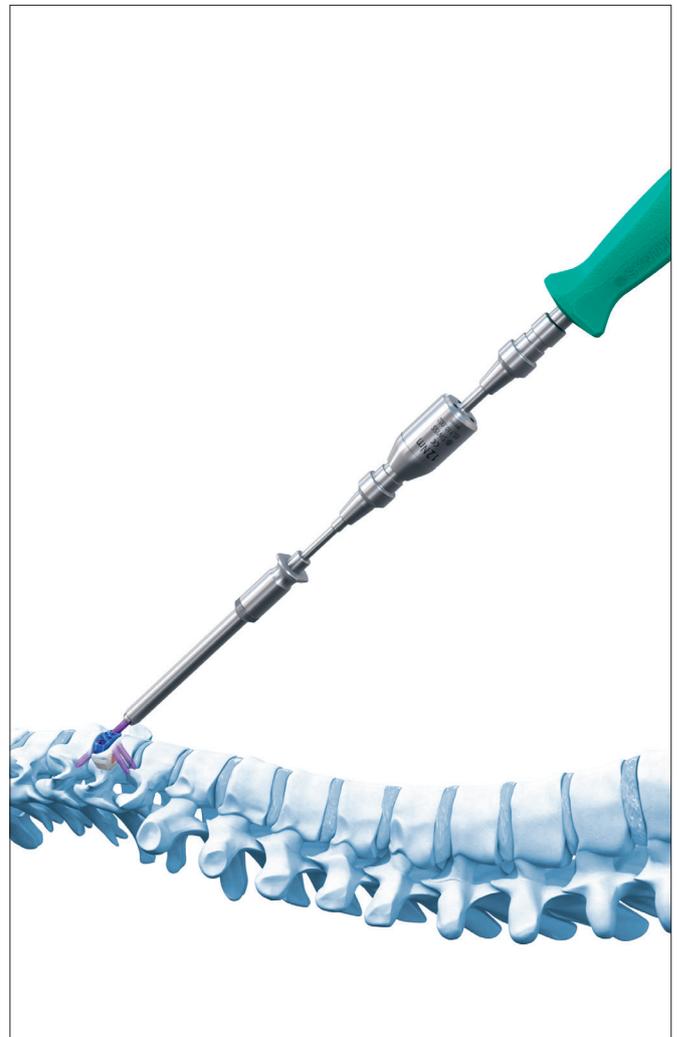
Advance the screw until the head of the screw contacts
the plate.

Repeat for the remaining screws.

- ⓘ **Warning:** Intraoperative imaging should be used to
verify screw position.

Precaution: The screws should be tightened only
after all screws have been inserted.

Note: If the aiming device is difficult to remove, verify
that the screw is advanced far enough so that the
aiming device is not contacting the screw during
removal.



A5. Tighten screws

Instruments

03.110.002	Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling
03.617.902	Screwdriver Shaft Stardrive, T8, self-holding
03.617.903	Handle with Quick Coupling

Optional Instrument

03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm
------------	--

To lock the screwhead in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

Precaution: If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

Note: Screws placed using the surgical technique may not always be flush with the plate, but will be sufficiently locked when 1.2 Nm torque is achieved.



Screw Fixation Option B: Drill Guide and Freehand Screw

If use of the aiming device is not the preferred surgical technique, follow these alternative technique steps.

B1. Drill first pilot hole

Instruments

03.617.962	Drill Guide with Handle
03.617.912	Drill Bit Ø 2.0 mm, drilling depth 12 mm, 3-flute, for Quick Coupling
03.617.914	Drill Bit Ø 2.0 mm, drilling depth 14 mm, 3-flute, for Quick Coupling
03.617.916	Drill Bit Ø 2.0 mm, drilling depth 16 mm, 3-flute, for Quick Coupling
03.617.903	Handle with Quick Coupling

It is recommended that the first hole be created for a caudally pointing screw.

Select a drill bit of appropriate length. Determine the entry point and trajectory for the screw. The correct angulations for the screws are 40° in the caudal or cranial direction. The medial screws point 2.5° laterally and the lateral screws point 2.5° medially.

Note: Lateral screws should always point medially.

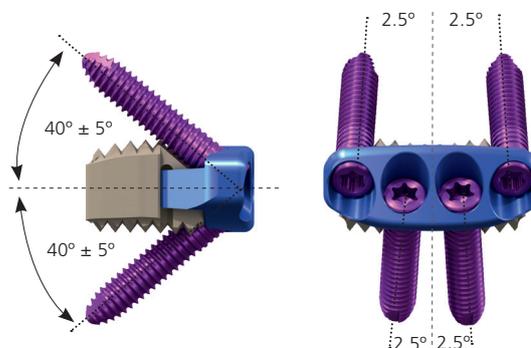
Insert the drill guide into the screw hole at the appropriate angle. The tip of the drill guide is designed to fit inside the screw hole of the plate and guide the correct angle.

Insert the drill bit into the guide and drill until the stop on the drill bit contacts the guide.

Remove the drill bit and guide.

Warning: Intraoperative imaging should be used to verify drill position.

Note: The drill bits are marked with a colored ring corresponding to the color-coded screw lengths. When the ring is flush with the top of the drill guide the appropriate depth has been reached.



B2. Insert first screw

Instruments

03.110.002 Torque Limiter, 1.2 Nm,
with AO/ASIF Quick Coupling

03.617.902 Screwdriver Shaft Stardrive,
T8, self-holding

03.617.903 Handle with Quick Coupling

Optional Instruments

03.617.901 Holding Sleeve for Screws for use with
No. 03.617.902

03.110.005 Handle for Torque Limiters 0.4/0.8/1.2 Nm

Select the appropriate screw length according to the preoperative planning and intraoperative findings.

Assemble the torque limiter to the screwdriver shaft and handle.

Precaution: If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

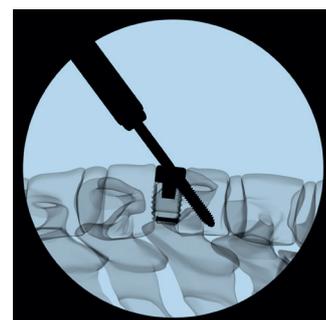
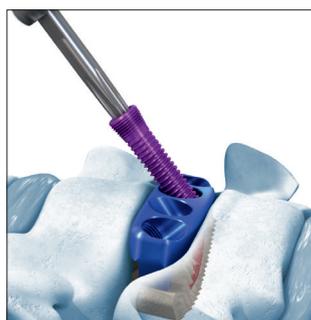
Load a screw onto the screwdriver with torque limiter. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.

Note: Retract the sleeve when inserting the first screw through the aiming device.

Advance the screw until the head of the screw contacts the plate.

ⓘ **Warning:** Intraoperative imaging should be used to verify screw position.

Precaution: The screws should be tightened only after all screws have been inserted.



B3. Insert remaining screws

Repeat steps B1 and B2 for the remaining screws.

B4: Tighten screws

Instruments

03.110.002	Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling
03.617.902	Screwdriver Shaft Stardrive, T8, self-holding
03.617.903	Handle with Quick Coupling

Optional Instrument

03.110.005	Handle for Torque Limiters 0.4/0.8/1.2Nm
------------	---

To lock the screwhead in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

Precaution: If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

Note: Screws placed using the surgical technique may not always be flush with the plate, but will be sufficiently locked when 1.2 Nm torque is achieved.



Screw Fixation Option C: Threaded Drill Guide and Freehand Screw

C1. Drill first pilot hole

Instruments

03.617.968	Drill Guide with threaded tip
03.617.912	Drill Bit 2.0 mm, drilling depth 12 mm, 3-flute, for Quick Coupling
03.617.914	Drill Bit 2.0 mm, drilling depth 14 mm, 3-flute, for Quick Coupling
03.617.916	Drill Bit 2.0 mm, drilling depth 16 mm, 3-flute, for Quick Coupling
03.617.903	Handle with Quick Coupling

It is recommended that the first hole be created for a caudally pointing screw.

Determine the trajectory for the threaded drill guide. The correct angulations are 40° in the caudal or cranial direction.

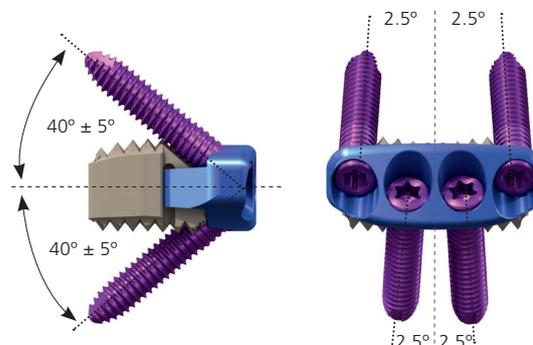
Screw the threaded drill guide into the thread of the ZERO-P plate at the appropriate angle until 2-finger tight. The thread of the drill guide is designed to fit inside the thread of the ZERO-P plate.

Determine a drill bit of appropriate length. Insert the drill bit into the guide and drill until the stop on the drill bit contacts the guide.

Remove the drill bit and and the threaded the drill guide.

- ⓘ **Warning:** Intraoperative imaging should be used to verify drill position.

Note: The drill bits are marked with a colored ring corresponding to the color-coded screw lengths. When the ring is flush with the top of the drill guide the appropriate depth has been reached.



C2. Insert first screw

Instruments

03.110.002 Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling

03.617.902 Screwdriver Shaft Stardrive, T8, self-holding 03.617.903 Handle with Quick Coupling

Optional Instruments

03.617.901 Holding Sleeve for Screws for use with No. 03.617.902

03.110.005 Handle for Torque Limiters 0.4/0.8/1.2 Nm

Select the appropriate screw length according to the preoperative planning and intraoperative findings.

Assemble the torque limiter to the screwdriver shaft and handle.

Precaution: If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

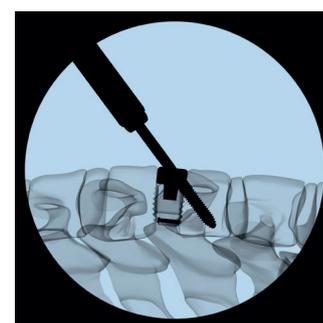
Load a screw onto the screwdriver with torque limiter. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.

Note: Retract the sleeve when inserting the first screw through the aiming device.

Advance the screw until the head of the screw contacts the plate.

Warning: Intraoperative imaging should be used to verify screw position.

Precaution: The screws should be tightened only after all screws have been inserted.



C3. Insert remaining screws

Repeat steps C1 and C2 for the remaining screws.

C4. Tighten screws

Instruments

03.110.002	Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling
------------	---

03.617.902	Screwdriver Shaft Stardrive, T8, self-holding
------------	---

03.617.903	Handle with Quick Coupling
------------	----------------------------

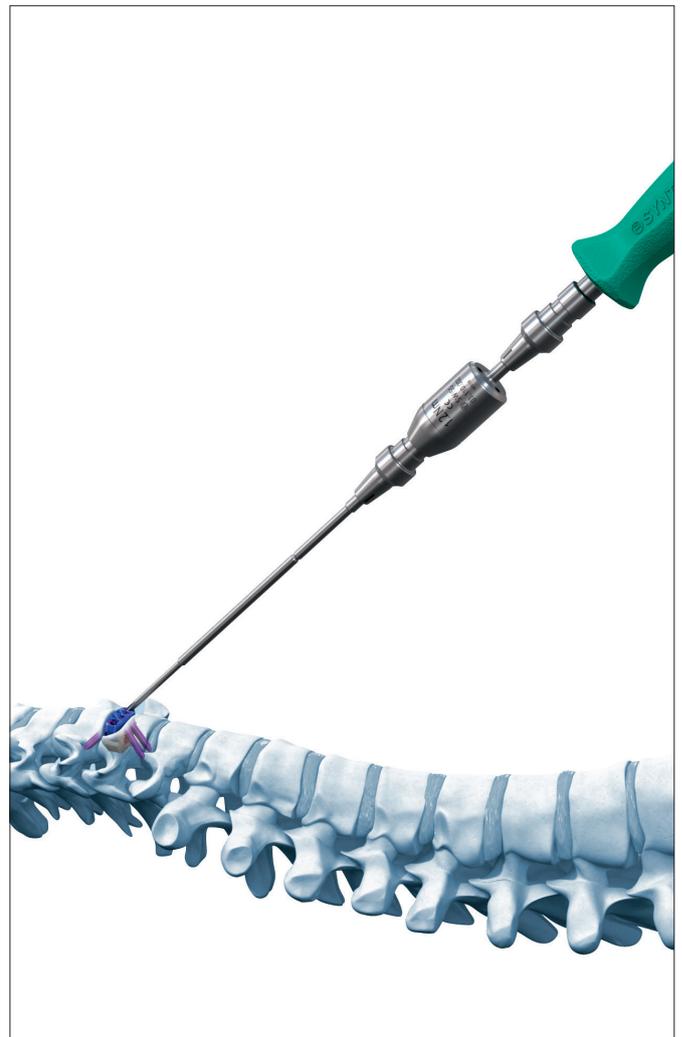
Optional Instrument

03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm
------------	---

To lock the screwhead in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

Precaution: If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

Note: Screws placed using the surgical technique may not always be flush with the plate, but will be sufficiently locked when 1.2 Nm torque is achieved.



Screw Fixation Option D: Awl and Freehand Screw

If surgeon preference is to awl and not to use the drilling technique, this alternative technique may be used.

D1. Awl first pilot hole

Instrument

03.617.990 Awl Ø 2.0 mm, with Sleeve

It is recommended that the first hole be created for a caudally pointing screws.

Determine the entry point and trajectory for the screw. The correct angulations for the screws are 40° in caudal or cranial direction. The medial screws point 2.5° laterally and the lateral screws point 2.5° medially.

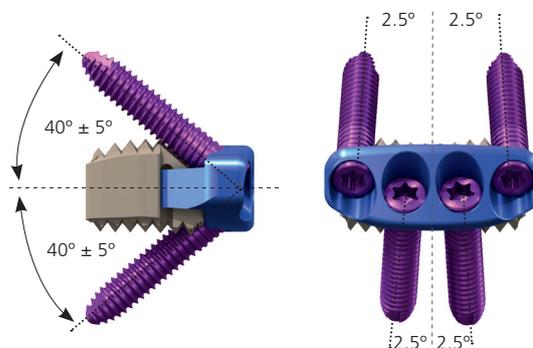
Note: Lateral screws should always point medially.

Insert the awl at the appropriate angle into a screw hole in the plate and push down, while simultaneously twisting the handle. Remove the awl, maintaining alignment of the hole and plate.

ⓘ **Warning:** Intraoperative imaging should be used to verify awl position.

Note: The tip of the awl is designed to fit inside the screw hole of the plate and guide the correct angle.

Precaution: Take care that the awl does not move the implant relative to the vertebral body. For particularly hard bone, drilling is recommended to minimize implant movement.



D2. Insert first screw

Instruments

03.110.002 Torque Limiter, 1.2 Nm,
with AO/ASIF Quick Coupling

03.617.902 Screwdriver Shaft Stardrive,
T8, self-holding

03.617.903 Handle with Quick Coupling

Optional instruments

03.617.901 Holding Sleeve for Screws for use with
No. 03.617.902

03.110.005 Handle for Torque Limiters 0.4/0.8/1.2 Nm

Select the appropriate screw length according to the preoperative planning and intraoperative findings.

Assemble the torque limiter to the screwdriver shaft and handle.

Precaution: If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

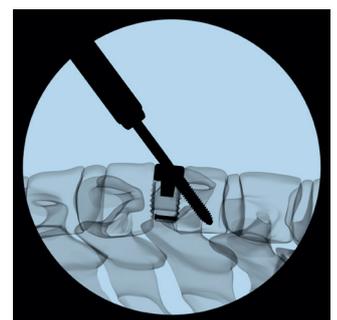
Load a screw onto the screwdriver with torque limiter. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.

Note: Retract the sleeve when inserting the first screw through the aiming device.

Advance the screw until the head of the screw contacts the plate.

ⓘ **Warning:** Intraoperative imaging should be used to verify screw position.

Precaution: The screws should be tightened only after all screws have been inserted.



D3. Insert remaining screws

Repeat step D1 and D2 for the remaining screws.

D4. Tighten screws

Instruments

03.110.002	Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling
03.617.902	Screwdriver Shaft Stardrive, T8, self-holding
03.617.903	Handle with Quick Coupling

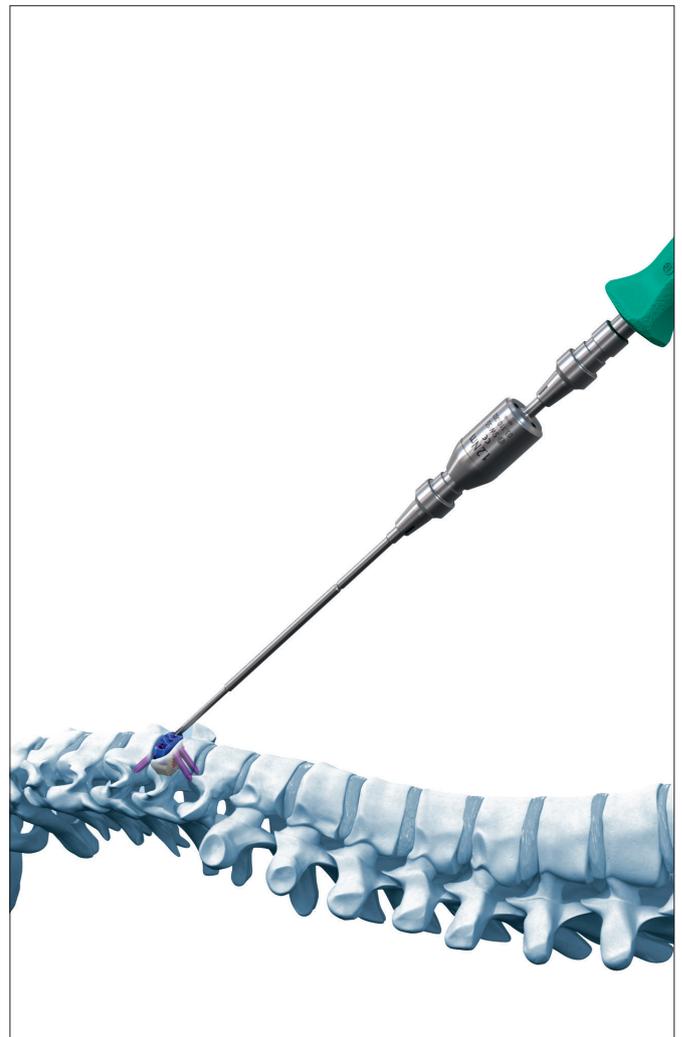
Optional Instrument

03.110.005	Handle for Torque Limiters 0.4/0.8/1.2Nm
------------	---

To lock the screwhead in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

Precaution: If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

Note: Screws placed using the surgical technique may not always be flush with the plate, but will be sufficiently locked when 1.2 Nm torque is achieved.



Screw Fixation Option E: Angled Instruments

For screws that are difficult to drill or insert because of interfering anatomy, the angled awl and angled screwdriver may be used.

E1. Awl first pilot hole

Instruments

03.617.993 Awl Ø 2.0 mm, angled

03.820.113 Mallet

It is recommended that the first hole be created for a caudally pointing screws.

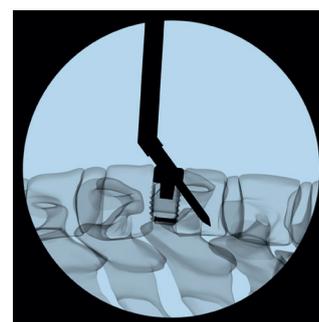
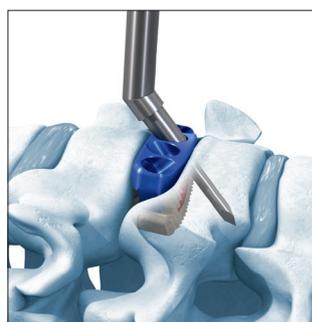
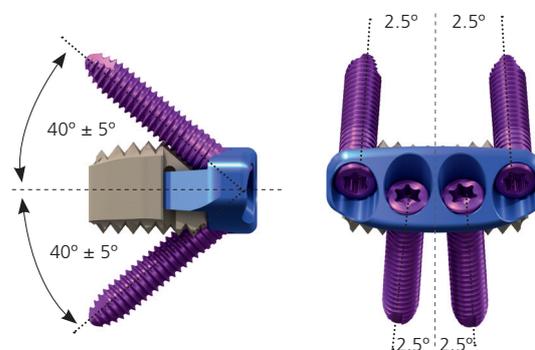
Determine the entry point and trajectory for the screw. The correct angulations for the screws are 40° in the caudal or cranial direction. The medial screws point 2.5° laterally and the lateral screws point 2.5° medially.

Note: Lateral screws should always point medially.

Insert the awl at the appropriate angle into the screw hole of the plate and tap with the mallet until the awl is seated.

Remove the awl, maintaining alignment of the hole and plate.

- ⚠ **Warning:** Intraoperative imaging should be used to verify awl position.



E2. Insert first screw

Instrument

03.617.900	Screwdriver Stardrive, T8, self-holding, angled, with Sleeve
------------	--

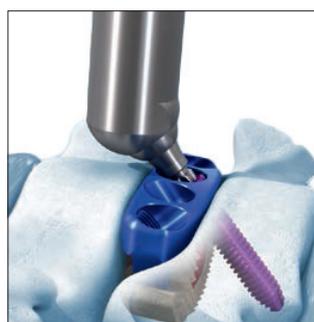
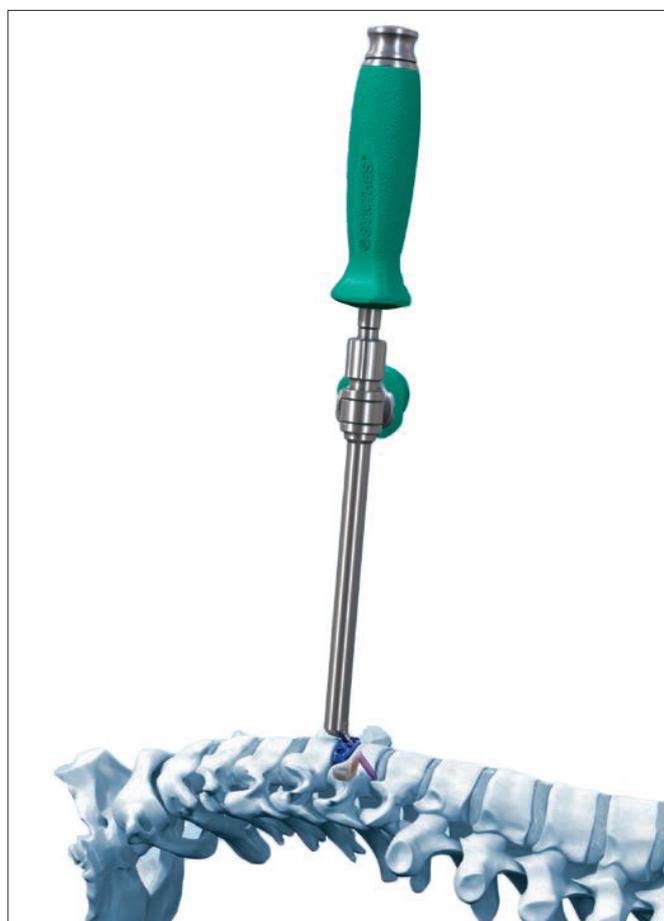
Optional instruments

03.110.002	Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm
03.617.903	Handle with Quick Coupling
03.617.905	Shaft for angled Screwdriver, with Quick Coupling

Select the appropriate screw length according to the preoperative planning and intraoperative findings.

Load a screw onto the angled screwdriver. Advance the screw until the head of the screw contacts the plate.

- ⚠ **Warning:** Intraoperative imaging should be used to verify screw position.



E3. Insert remaining screws

Repeat steps E1 and E2 for the remaining screws.

E4. Tighten screws

Instruments

03.617.900	Screwdriver Stardrive, T8, self-holding, angled, with Sleeve
------------	--

03.110.002	Torque Limiter, 1.2 Nm, with AO/ASIF Quick Coupling
------------	---

03.617.902	Screwdriver Shaft Stardrive, T8, self-holding
------------	---

03.617.903	Handle with Quick Coupling
------------	----------------------------

Optional Instruments

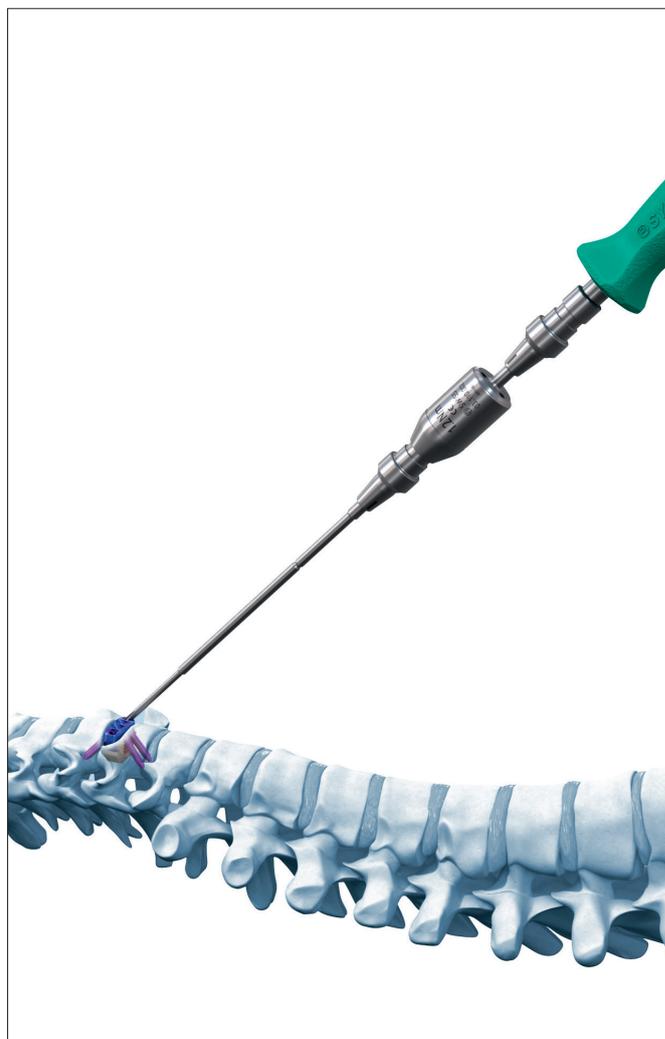
03.110.005	Handle for Torque Limiters 0.4/0.8/1.2 Nm
------------	---

03.617.905	Shaft for angled Screwdriver, with Quick Coupling
------------	---

To lock the screwhead in the plate, always use the torque limiter with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

Precaution: If the torque limiter is not used, breakage of the screwdriver may occur and could potentially harm the patient.

Note: Screws placed using the surgical technique may not always be flush with the plate, but will be sufficiently locked when 1.2 Nm torque is achieved.



Implant Removal

If a Zero-P implant must be removed, the following technique is recommended.

1. Remove screw

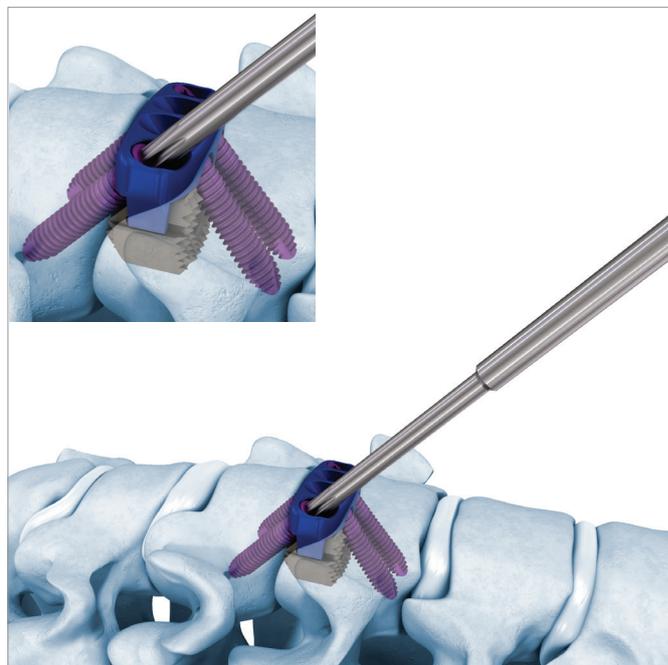
Instruments

03.617.902	Screwdriver Shaft Stardrive, T8, self-holding
03.617.903	Handle with Quick Coupling

Attach the handle to the screwdriver shaft, then engage the assembled driver into the drive recess of the screw to be removed. Rotate the driver counterclockwise to first loosen the screw from the ZERO-P implant. Continue to rotate the driver counterclockwise to remove the loosened screw from the implant.

Note: If multiple screws need to be removed, it is recommended to first loosen all screws before removing any of the screws from the implant. Loosening all screws before removal of any screw helps ensure that the implant will be properly secured during removal.

Precaution: Screw loosening with the torque limiting handle may damage the torque limiting handle. Therefore always use the standard handle for screw loosening.



Optional technique

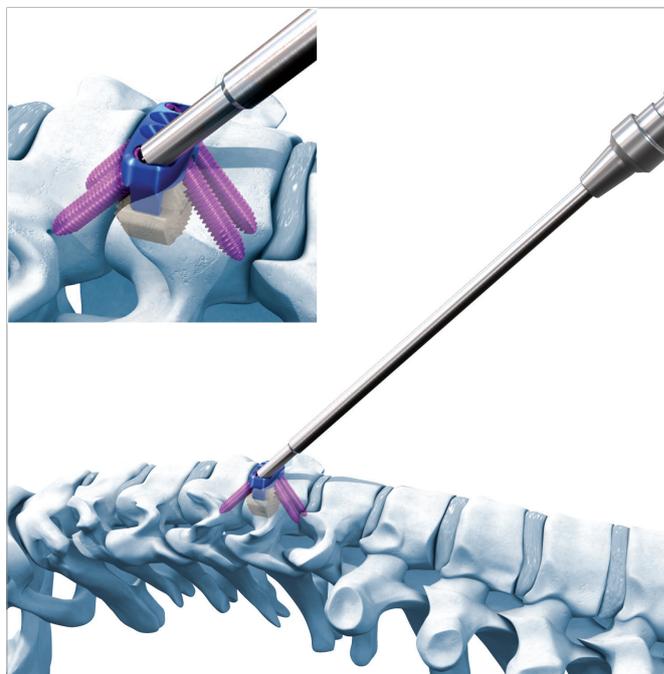
1a. Remove screw with Conical Extraction Screw

Instruments

03.617.971S	Extraction Screw, conical
03.617.975S	Drill Bit Ø 2.0 mm, 2-flute, for Quick Coupling
03.617.903	Handle with Quick Coupling

In the event the screwdriver cannot properly engage the drive recess of the screw to loosen the screw, or if the screw recess is damaged, the conical extraction screw may be used to remove the screw.

First, use the 2.0 mm drill bit to prepare the screw recess. Under full power and on axis with the screw, insert the drill bit into the screw head to lightly pre-drill the screw recess. Advance the drill bit until the stop of the drill bit contacts the top of the screw. This facilitates deeper anchoring of the conical extraction screw into the screw recess.



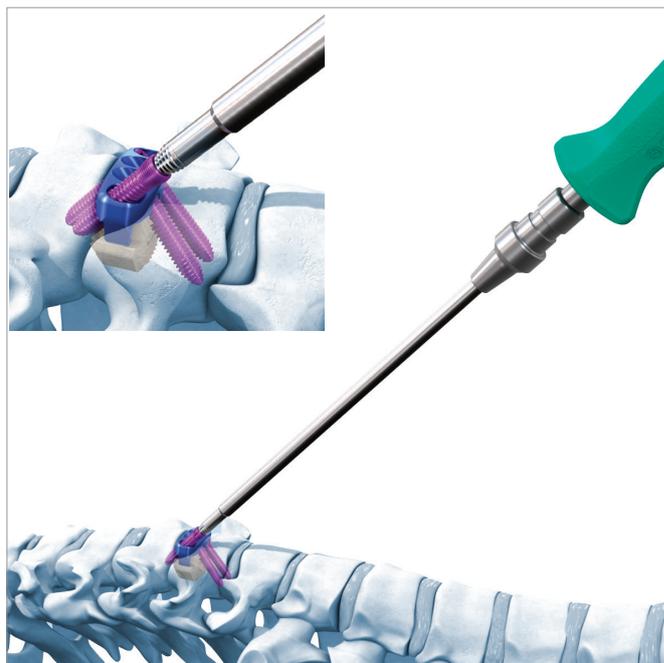
Warning: Drilling into the screw recess with the 2.0 mm drill bit will cause metal debris. Use of suction and irrigation is recommended to remove the debris from the wound.

Connect the conical extraction screw to the handle with quick coupling. Insert the tip of the conical extraction screw into the screw recess on axis with the screw. Turn counterclockwise until the extraction screw grasps into the screw recess. Continue to turn counterclockwise to remove the screw.

Precautions:

- Do not use the conical extraction screw with power tools. Use of power tools with the conical extraction screw may potentially damage the screw recess and/or extraction screw, preventing subsequent removal.
- Do not use the conical extraction screw with torque-limiting attachment, as this prohibits removal of the screws and may cause additional damage to the instrumentation.

Note: The conical extraction screw is single-use only.



2. Extract implant

Instrument

03.617.963	Aiming Device for Zero-P
------------	--------------------------

Once all screws are removed, the ZERO-P implant may be removed using the aiming device. Attach the aiming device to the implant by aligning the screw holes of the implant with the retention features on the aiming device and then expanding the aiming device.

After the implant is securely attached, carefully remove the implant.

Note: Use of distraction at the disc space is recommended to facilitate removal.

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.depuy-synthes.com/ifu

Bibliography

1. Aebi M, JS Thalgott, JK Webb. (1998). AO ASIF Principles in Spine Surgery. Berlin: Springer-Verlag.
2. Aebi M, Arlet V, Webb JK (2007). AOSPINE Manual (2 vols), Stuttgart, New York: Thieme.

