

Variable angle zero-profile anterior cervical
interbody fusion (ACIF) device.

ZERO-P VA™ 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 VA™ Stand-Alone Implant	2
	AO Spine Principles	4
Surgical Technique	Considerations for Use Adjacent to Prior Fusion	5
	Patient Positioning, Exposure and Discectomy	6
	Implant Insertion	8
	Screw Fixation	13
	• Option A: Awl and Self-drilling Screws	14
	• Option B: Drill Guide	18
	• Option C: Angled Instruments	23
Implant Removal	27	
Indications and Contraindications		31
Bibliography		32

For Product Catalog contact your local
DePuy Synthes representative.

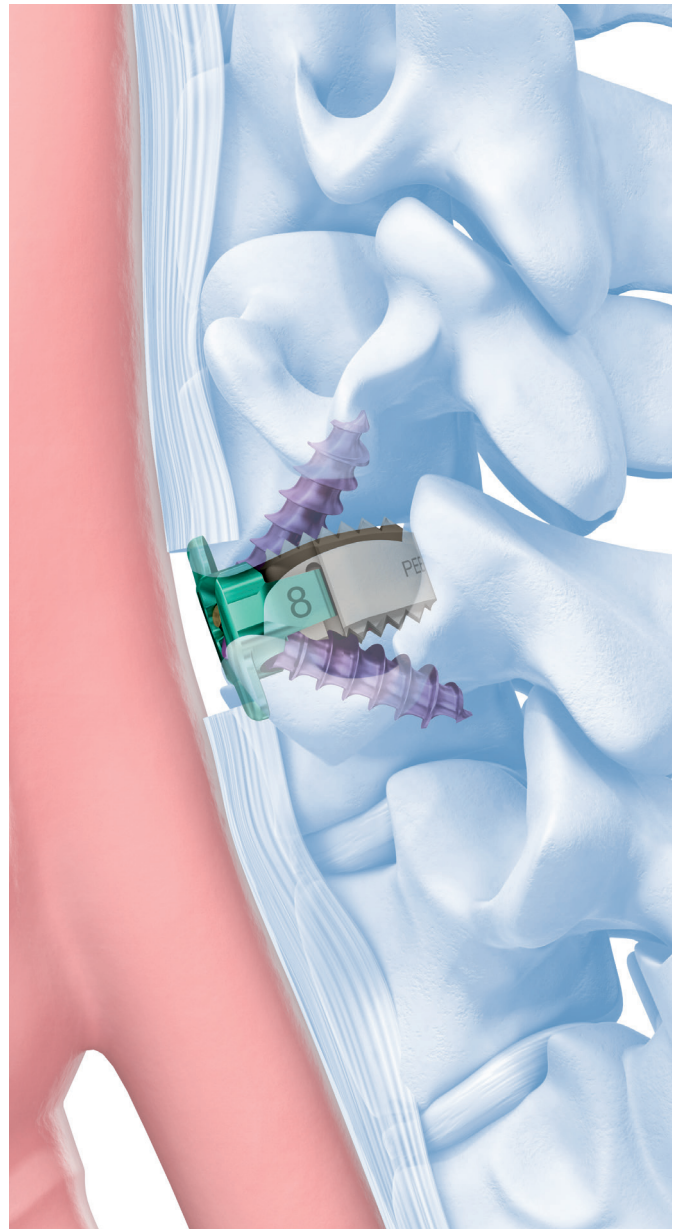
ZERO-P VA™ Stand-Alone Implant

Variable angle zero-profile anterior cervical interbody fusion (ACIF) device.

The ZERO-P VA 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 midline

The ZERO-P VA Implant is designed to be placed within the intervertebral space with only the two lateral tabs contacting the anterior surface of the vertebral bodies.



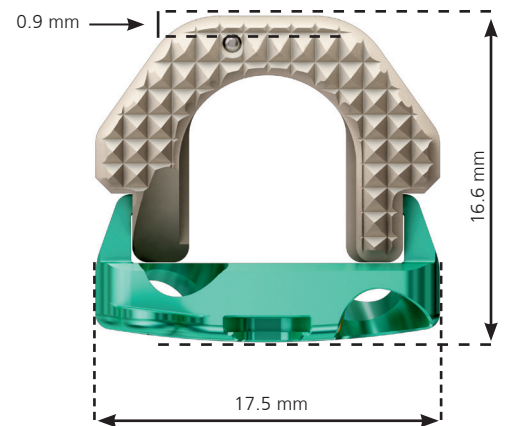
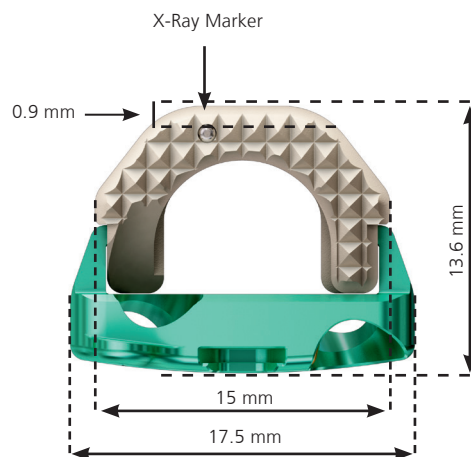
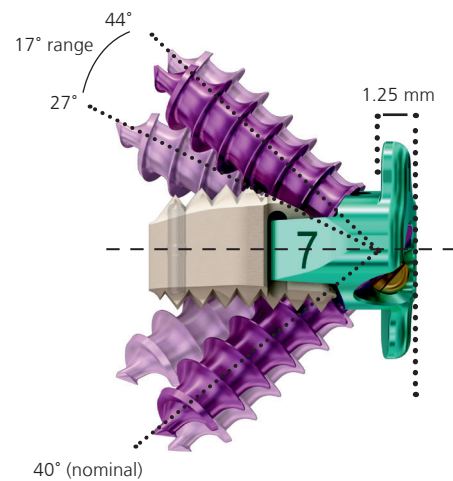
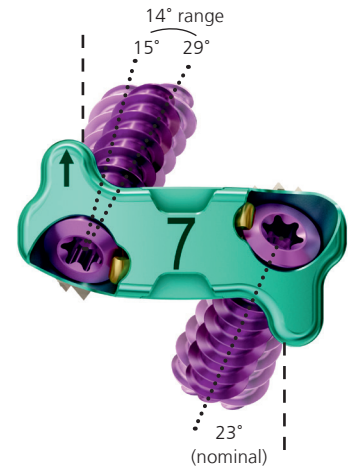
ZERO-P VA Stand-Alone Implant
 Variable angle zero-profile anterior cervical
 interbody fusion (ACIF) device.

PEEK interbody Cage

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

Titanium alloy interbody plate with stops and variable angle screws

- Screws can be inserted 27°– 44° (17° range) in cranial-caudal direction and 15°– 29° (14° range) in medial-lateral direction.



PEEK-Optima® is a registered trademark of InVivo Ltd.

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}

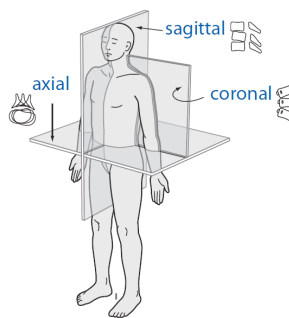
Stability

Stabilization to achieve a specific therapeutic outcome



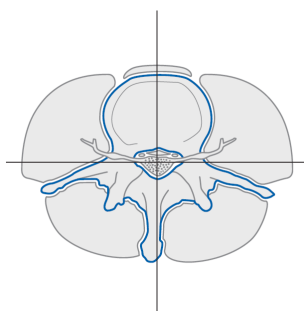
Alignment

Balancing the spine in three dimensions



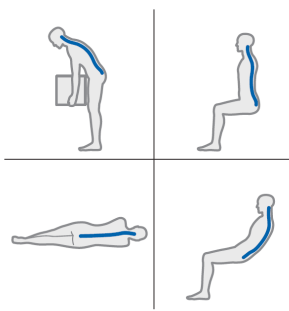
Biology

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 Prior Fusion

If a ZERO-P VA Implant is intended to be placed adjacent to a prior fusion, care must be taken to avoid placement of ZERO-P VA Implant and screws in direct contact of previously placed hardware.

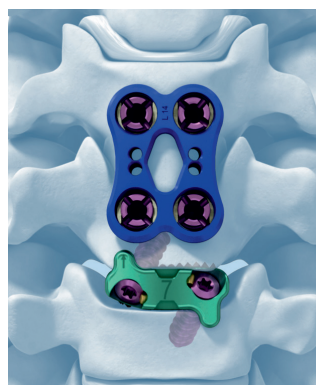
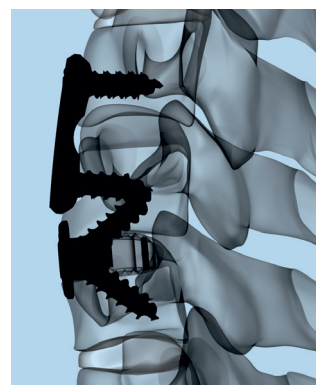
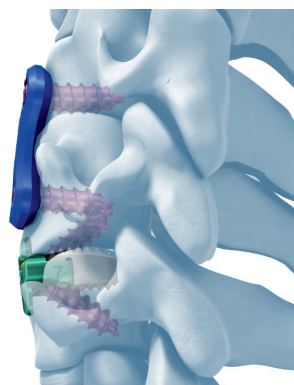
Precaution: Placement of ZERO-P VA adjacent to a previous, multi-level fusion can result in excessive loading. Additional posterior supplemental fixation should be considered in cases where ZERO-P VA is placed adjacent to a previous, multi-level fusion.

As necessary, remove components of the implanted hardware associated with the previously fused level that may prevent ZERO-P VA from being properly implanted per recommended techniques as described in pages 6–30.

- **Warning:** 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 with the help of an intraoperative x-ray.

Warnings:

1. If adjacent hardware prevents both ZERO-P VA Screws from being implanted, a different device should be used, as excessive loading may be placed on the implant leading to potential post-op device failure or migration, leading to patient harm.
2. If any screw cannot be inserted at the correct trajectory or blocked by the interbody plate per one of the recommended techniques as described in pages 14–26, a different device should be used to avoid the risk of screw backout.
3. Confirm that the ZERO-P VA Implant is not placed in direct contact with implanted hardware associated with the previously fused level. If the ZERO-P VA Implant remains in direct contact with hardware associated with the previously fused level, excessive loading may be placed on the ZERO-P VA Implant leading to potential post-op device failure or migration, leading to patient harm.

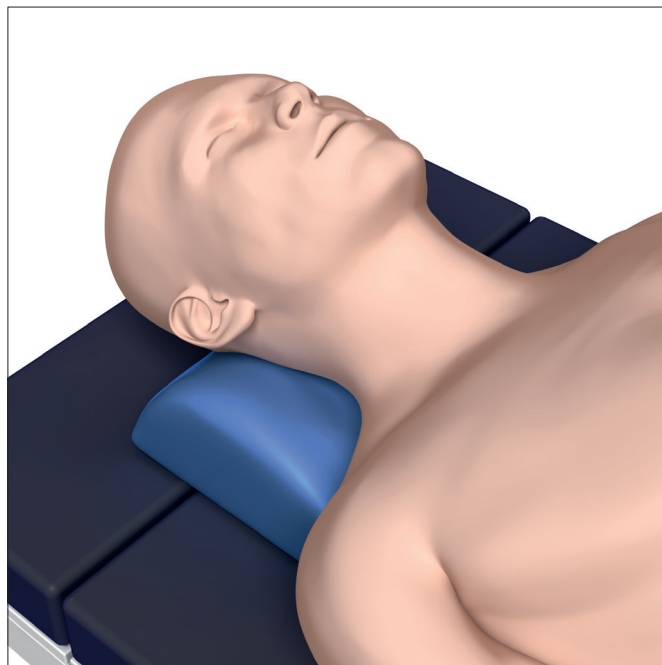


Patient Positioning, Exposure and Discectomy

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

1. Patient Positioning

- ① 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.



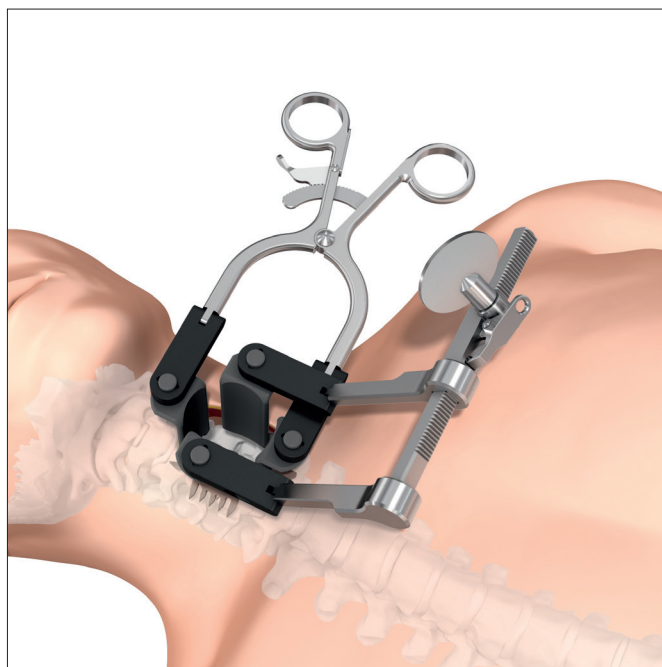
2. Access

Optional set

187.797 Cervical Retractors and Distractors

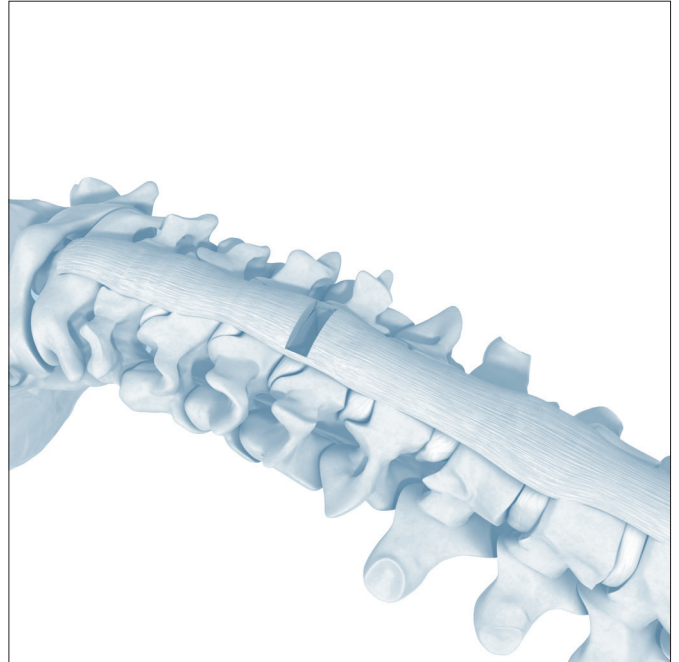
- ① Locate the correct operative level using radiographic imaging.
Expose the intervertebral disc and the adjacent vertebral bodies through a standard anterior approach to the cervical spine.

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.

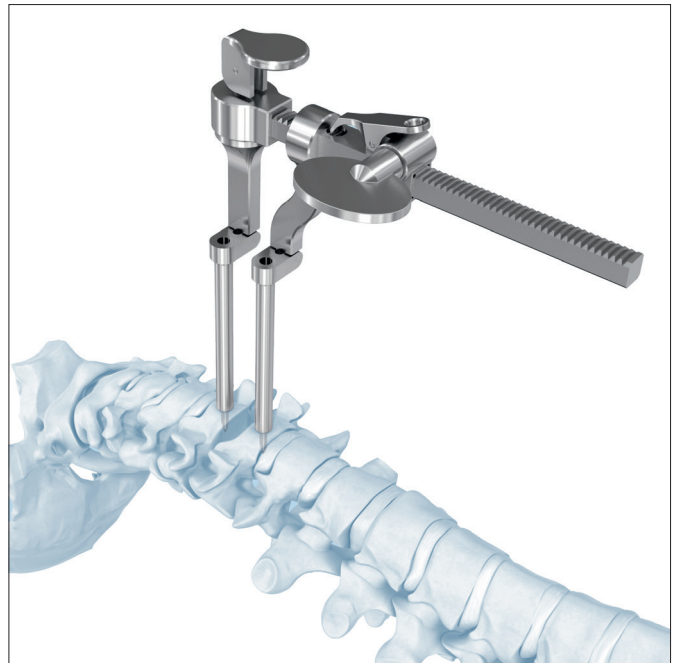


Optional set

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

03.647.750 – 03.647.759	Zero-P VA Trial Spacers, lordotic, heights 5 –12 mm, blue
03.647.780 – 03.647.789	Zero-P VA Trial Spacers, convex, heights 5 –12 mm, gold
03.647.760– 03.647.769	Zero-P VA Trial Spacers, large, lordotic, heights 5 –12 mm, blue
03.647.790– 03.647.799	Zero-P VA Trial Spacers, large, convex, heights 5 –12 mm, gold

Optional instruments

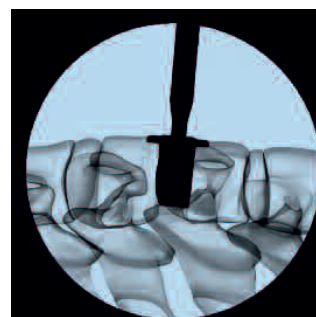
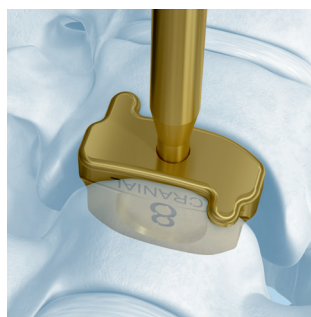
03.820.113	Mallet
03.617.940	Handle with Large Quick Coupling

Selection of the trial spacer depends on the height and depth of the intervertebral space, the preparation technique, and patient anatomy. Choose a 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.

Trial spacers have depth stops corresponding to the depth stops of the ZERO-P VA Implant.



Precaution: Anterior osteophytes in the surgical site that prevent desired positioning of a trial spacer will likely prevent desired positioning of the ZERO-P VA Implant. It is recommended to remove interfering anterior osteophytes before implant insertion.

Notes:

- 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 VA 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 footprint size trial spacers before using large footprint size trial spacers.

- Ⓢ **Precaution:** Although the trial spacers have depth stops, use of an image intensifier is recommended to check the position during insertion. With the segment fully distracted, the trial spacer must fit tightly between the end plates.

2. Pack implant with bone graft

Instruments

03.647.970	Cancellous Bone Impactor
------------	--------------------------

03.647.984	Packing Block for Zero-P VA
------------	-----------------------------

It is recommended to pack the ZERO-P VA Implant with bone or bone graft substitute.

Place the ZERO-P VA Implant into the packing block.

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

Notes:

- To ensure contact with the vertebral endplates, it is important to fill the implant until the graft material protrudes from the lumen in the cage.
- The bone impactor and the packing block can only be used with the standard size footprints of ZERO-P VA.



3. Implant insertion

Instrument

03.647.963 Insertion Device for Zero-P VA

Optional instruments

03.617.981 Impactor, flat

03.647.980 Implant Holder for Zero-P VA

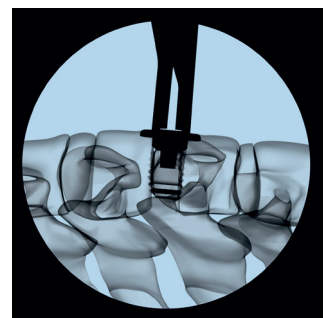
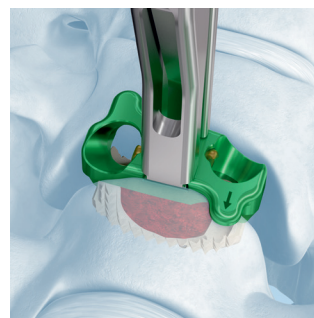
03.647.982 Impactor with ball tip for Zero-P VA

Use the insertion device or implant holder to introduce the implant into the disc space.

Using the insertion device

Attach the insertion device to the implant by aligning the recessed grooves located midline on the anterior face of the implant with the pronged tabs of the device tip. Squeeze the insertion device handles to secure the implant; the thumb nut on the insertion device may then be advanced clockwise to affix the implant to the insertion device.

Carefully insert the implant into the distracted segment. Advance the implant until the implant stops rest on the anterior surface of the vertebral body. The implant should fit tightly between the endplates.



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

Using the implant holder

Alternatively, the implant can be carefully inserted into the disc space with the forceps-style implant holder. Attach the implant holder to the implant by aligning the recessed grooves located midline on the anterior face of the implant with the ends of the implant holder. Once the implant is partially introduced into the disc space, the implant can be advanced using the flat impactor and/or ball tip impactors.

Note: The ZERO-P VA Interbody Plate is marked with an arrow to indicate implant orientation. When inserting the Zero-P VA Implant, the arrow should point to the cranial vertebral body upon insertion.

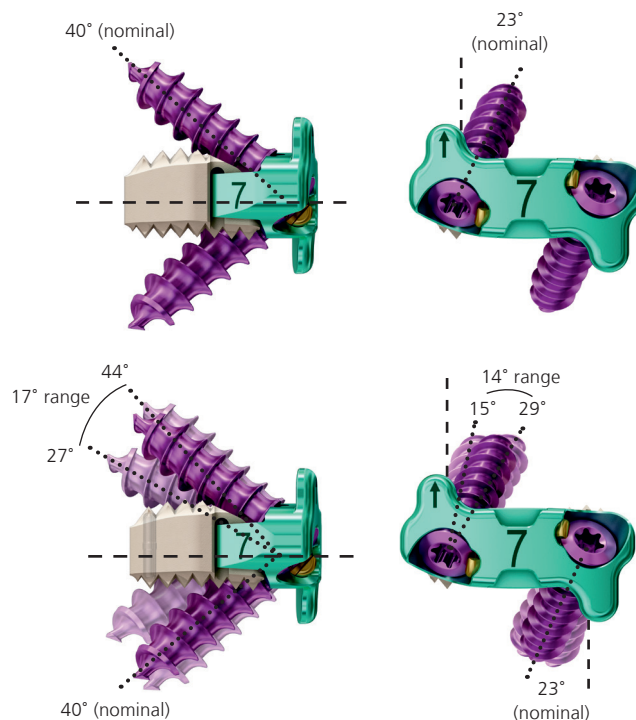
- ⓘ **Warning:** Verify final Implant position relative to the vertebral bodies in the AP and lateral views using intraoperative imaging. The PEEK cage has a single posterior radiopaque marker incorporated into the implant to enable intraoperative radiographic assessment of the implant position.

Screw Fixation

The ZERO-P VA System is only intended to be implanted with two ZERO-P VA Screws, forming a stand-alone interbody fusion construct. By design, the ZERO-P VA System enables insertion of ZERO-P VA Screws within a range of acceptable trajectories.

Using an awl or drill to prepare screw holes is recommended; these instruments are designed to facilitate subsequent placement of screws at the desired trajectory.

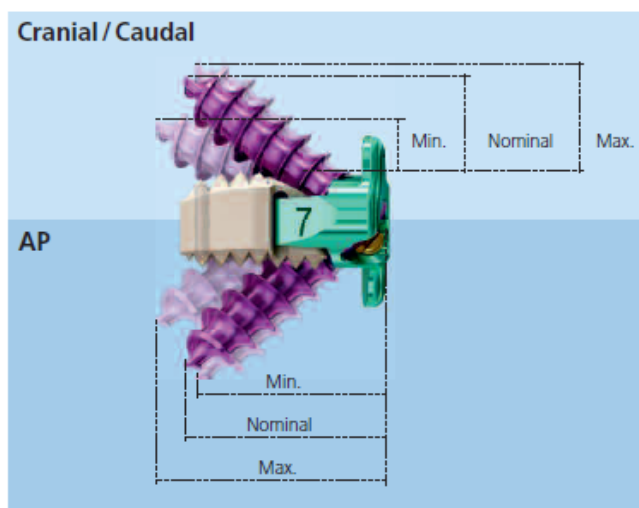
The screw trajectory achieved during screw insertion will result in varied screw penetration into the vertebral bodies.



Screw Penetration (mm)

Screw Length	AP			Cranial / Caudal		
	Min.	Nominal	Max.	Min.	Nominal	Max.
14 mm	11.3	12.9	14.0	3.1	5.9	6.3
16 mm	12.7	14.3	15.7	4.0	7.2	7.7
18 mm	14.1	15.3	17.5	4.9	8.0	9.0

Precaution: Depending on the selected combination of implant, screw length, and trajectory used, the screws may extend beyond the posterior edge of the implant.



Screw Fixation

Option A: Awl and Self-drilling Screws

A recommended screw fixation technique is to create pilot holes and then insert self-drilling screws.

1. Create first pilot hole

Instruments

03.647.963 Insertion Device for Zero-P VA

03.647.990 Awl Ø 2.5 mm, with Sleeve

Optional instrument

03.647.980 Implant Holder for Zero-P VA

It is recommended to create the first hole for the caudally aimed screw.

Determine the entry point and trajectory for the first screw. The correct angulations for the screws range between 27°–44° cranial / caudal and 15°–29° medial / lateral.

Insert the awl into the first screw hole of the interbody plate. To ensure proper angle of the pilot hole, fully seat the outer sleeve tip of the awl into the interbody plate. To fully seat the outer sleeve of the awl it is required to push and hold the sleeve at the same time.

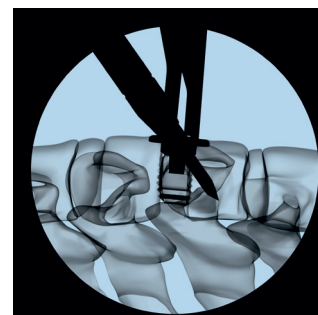
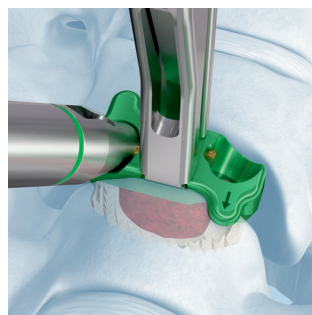
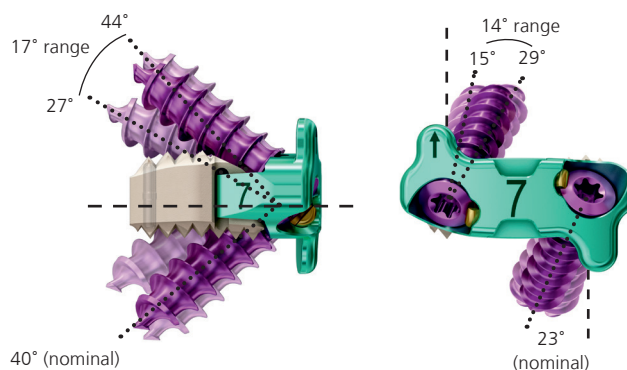
Once the sleeve is fully seated and the correct trajectory is confirmed, push down on the ball handle of the awl while simultaneously twisting the handle to advance the awl. Remove the awl while maintaining alignment of the hole and implant.

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

Notes:

- When using the awl, the insertion device or implant holder should be used to minimize implant movement.
- The tip of the awl fits into the screw hole of the interbody plate to produce the correct angle.
- The upper shaft of the awl, near the awl handle, is marked with two black rings. When advancing the awl, the appropriate depth has been reached when the end of the outer sleeve falls between the two black rings.

Precaution: Do not use the awl without the sleeve; it may cause injury to the patient.



2. Insert first screw

Instruments

03.617.902 Screwdriver Shaft Stardrive, T8, self-holding

03.647.903 Handle, small, with Quick Coupling

03.647.963 Insertion Device for Zero-P VA

Optional instruments

03.647.901 Holding Sleeve for Screws for use with No. 03.617.902

03.647.980 Implant Holder for Zero-P VA

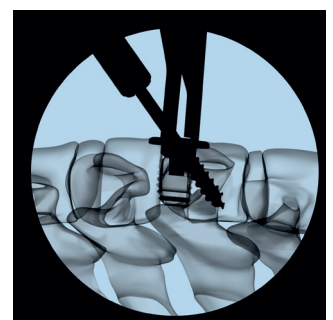
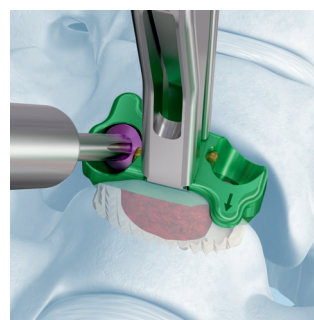
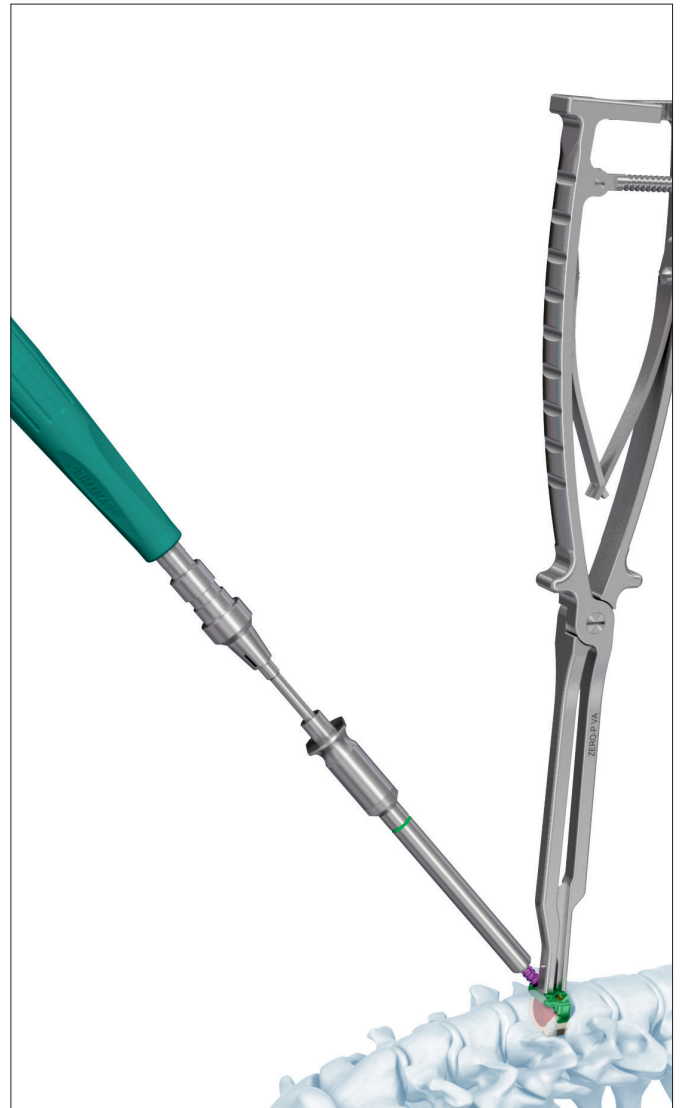
Select the appropriate screw length according to the preoperative plan and intraoperative findings.

Attach the screwdriver shaft to the handle then load the selected screw to the assembled driver. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.

Advance the screw until the screw head passes beyond the blocking feature of the interbody plate. Confirm visually that the blocking feature covers the screw head.

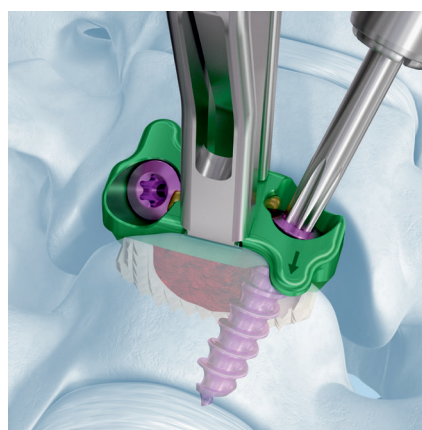
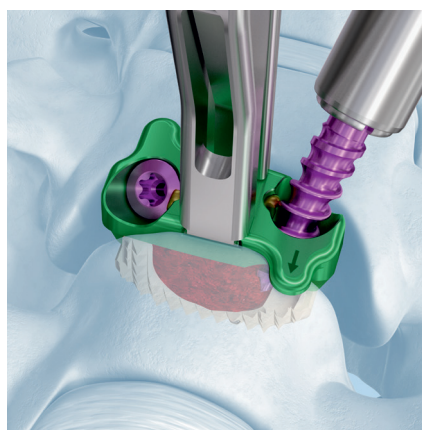
Note: When inserting screws, the insertion device or implant holder should be used to minimize implant movement.

- ⓘ **Warning:** Intraoperative imaging should be used to verify screw position and to verify the screw follows the trajectory of the pilot hole created by the awl.



3. Insert second screw

Repeat steps 1 and 2 for the second screw.



4. Tighten screws and lag plate (optional)

Instruments

03.617.902 Screwdriver Shaft Stardrive, T8, self-holding

03.647.903 Handle, small, with Quick Coupling

03.647.963 Insertion Device for Zero-P VA

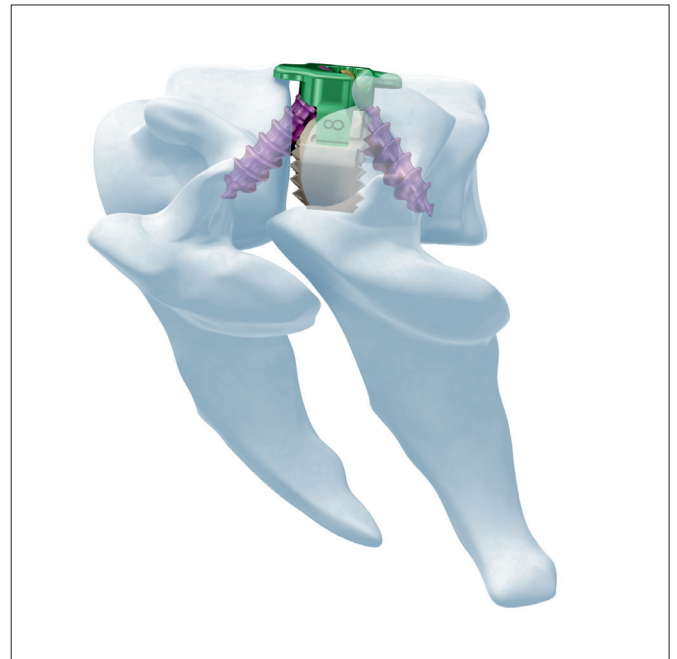
Optional instrument

03.647.980 Implant Holder for Zero-P VA

If necessary use the screwdriver to advance each screw another $\frac{1}{4}$ – $\frac{1}{2}$ turn. This tightening step lags the stops of the interbody plate to the anterior surface of the vertebral bodies and increases the apposition of the implant to the vertebral body endplates.

Note: When tightening screws, the insertion device or implant holder should be used to minimize implant movement.

Precaution: Do not continue advancing any screw after the stops of the interbody plate are lagged to the anterior surface of the vertebral bodies and do not advance any screw more than $\frac{1}{2}$ turn during tightening. Over-tightening may strip bone and compromise fixation of the implant in vertebral bodies.



Screw Fixation

Option B: Drill Guide

Alternatively, use a drill guide and drill to create a pilot hole. Then insert the screws.

1. Drill first pilot hole

Instruments

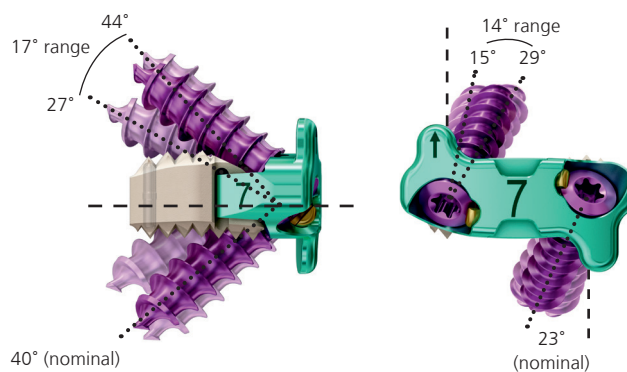
03.617.912	Drill Bit Ø 2.0 mm, drilling depth 12mm, 3-flute, for Quick Coupling
03.617.914	Drill Bit Ø 2.0 mm, drilling depth 14mm, 3-flute, for Quick Coupling
03.617.916	Drill Bit Ø 2.0 mm, drilling depth 16 mm, 3-flute, for Quick Coupling
03.647.903	Handle, small, with Quick Coupling
03.647.962	Drill Guide with Handle
03.647.963	Insertion Device for Zero-P VA

Optional instrument

03.647.980	Implant Holder for Zero-P VA
------------	------------------------------

It is recommended to create the first hole for the caudally aimed screw.

Determine the entry point and trajectory for the first screw. The correct angulations for the screws range between 27°–44° cranial /caudal and 15°–29° medial/lateral.



Select a drill bit of appropriate length and assemble the drill bit to the handle.

Insert the drill guide into the screw hole of the interbody plate. To ensure proper angle of the pilot hole, fully seat the tip of the drill guide into the interbody plate and confirm correct trajectory. Insert the drill bit into the guide and drill until the stop of the drill contacts the guide.

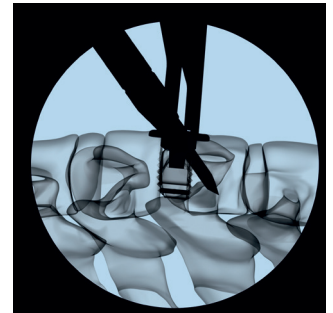
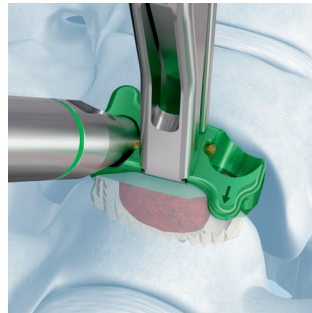
Remove the drill bit and drill guide.

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

Notes:

- 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.
- When drilling, the insertion device or implant holder should be used to minimize implant movement.

Precaution: When drilling, make sure to drill on-axis, in the same trajectory as the drill guide. Applying side loads and/or levering off-axis during drilling may result in broken or damaged instruments which may potentially cause harm to the patient.



2. Insert first screw

Instruments

03.617.902 Screwdriver Shaft Stardrive, T8, self-holding

03.647.903 Handle, small, with Quick Coupling

03.647.963 Insertion Device for Zero-P VA

Optional instruments

03.647.901 Holding Sleeve for Screws for use with No. 03.617.902

03.647.980 Implant Holder for Zero-P VA

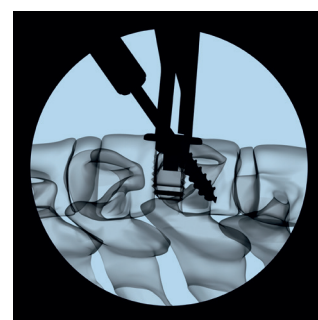
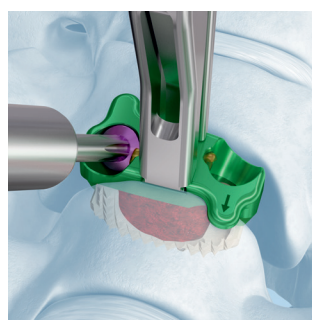
Select the appropriate screw length according to the preoperative plan and intraoperative findings.

Attach the screwdriver shaft to the handle, then load the selected screw to the assembled driver. The screwdriver is designed to be self-retaining. Alternatively, the holding sleeve may also be used for screw retention.

Advance the screw until the screw head passes beyond the blocking feature of the interbody plate. Confirm visually that the blocking feature covers the screw head.

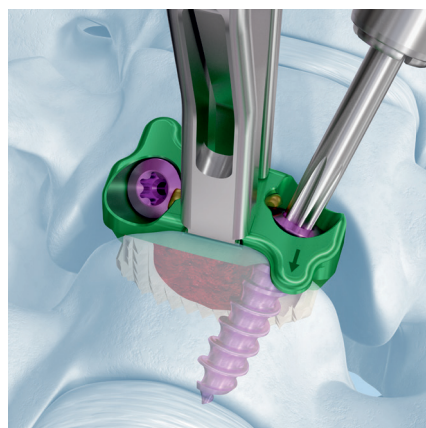
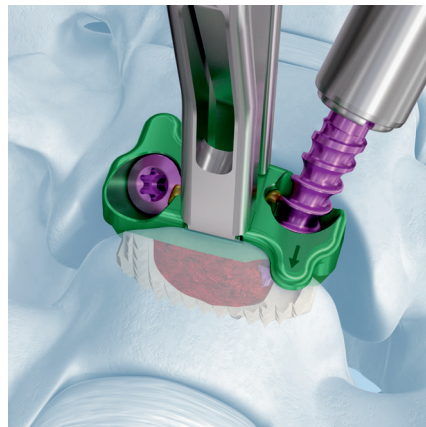
Note: When inserting screws, the insertion device or implant holder should be used to minimize implant movement.

- ⓘ **Warning:** Intraoperative imaging should be used to verify screw position and to verify the screw follows the trajectory of the pilot hole created by the drill.



3. Insert second screw

Repeat steps 1 and 2 for the second screw.



4. Tighten screws and lag plate (optional)

Instruments

03.617.902 Screwdriver Shaft Stardrive, T8, self-holding

03.647.903 Handle, small, with Quick Coupling

03.647.963 Insertion Device for Zero-P VA

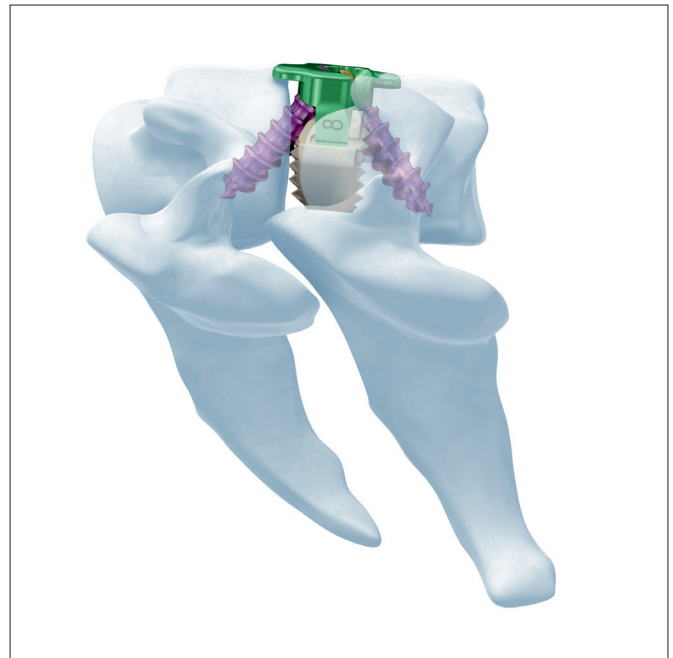
Optional instrument

03.647.980 Implant Holder for Zero-P VA

If necessary use the screwdriver to advance each screw another $\frac{1}{4}$ – $\frac{1}{2}$ turn. This tightening step lags the stops of the interbody plate to the anterior surface of the vertebral bodies and increases the apposition of the implant to the vertebral body endplates.

Note: When tightening screws, the insertion device or implant holder should be used to minimize implant movement.

Precaution: Do not continue advancing any screw after the stops of the interbody plate are lagged to the anterior surface of the vertebral bodies and do not advance any screw more than $\frac{1}{2}$ turn during tightening. Over-tightening may strip bone and compromise fixation of the implant in vertebral bodies.



Screw Fixation

Option C: Angled Instruments

When screws holes are difficult to prepare or screws difficult to insert due to interfering anatomy, the angled awl and angled screwdriver may be used.

1. Create first pilot hole

Instruments

03.647.963 Insertion Device for Zero-P VA

03.647.993 Awl Ø 2.5 mm, angled

03.820.113 Mallet

Optional instrument

03.647.980 Implant Holder for Zero-P VA

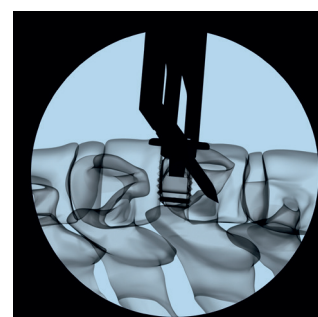
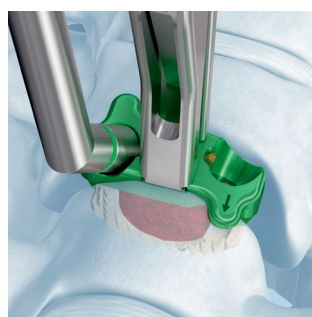
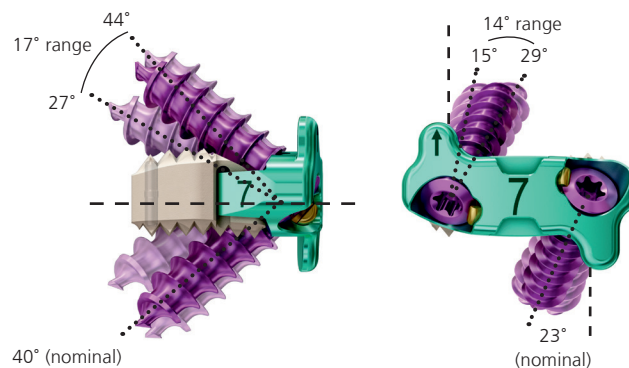
It is recommended to create the first hole for the caudally aimed screw.

Determine the entry point and trajectory for the screw. The correct angulations for the screws range between 27°–44° cranial/caudal and 15°–29° medial/lateral.

Insert the awl at the appropriate angle into the first screw hole of the plate and tap with the mallet until the awl is seated. Remove the awl while maintaining alignment of the hole and implant.

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

Note: When using the angled awl, the insertion device or implant holder should be used to minimize implant movement.



2. Insert first screw

Instrument

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

Optional instruments

03.617.905 Shaft for angled Screwdriver, with Quick Coupling

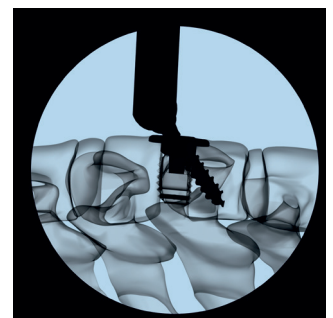
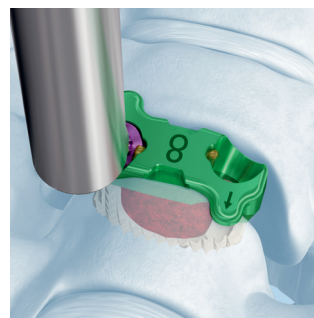
03.647.903 Handle, small, with Quick Coupling

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

Load the selected screw onto the angled screwdriver. Advance the screw until the screw head passes beyond the blocking feature of the interbody plate. Confirm visually that the blocking feature covers the screw head.

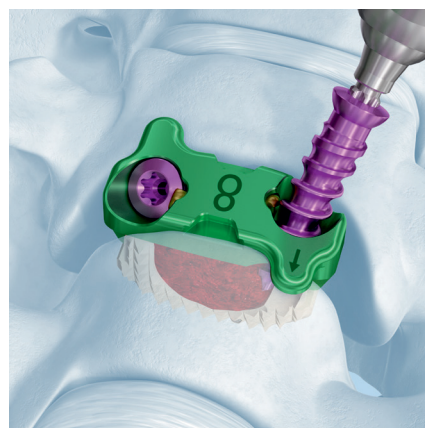
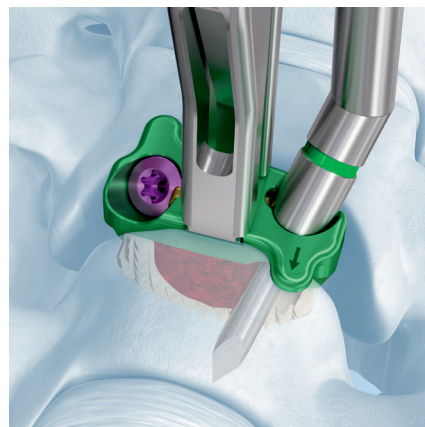
- ⓘ **Warning:** Intraoperative imaging should be used to verify screw position and to verify the screw follows the trajectory of the pilot hole created by the angled awl.

Note: When inserting screws, the insertion device or implant holder should be used to minimize implant movement.



3. Insert second screw

Repeat steps 1 and 2 for the second screw.



4. Tighten screws and lag plate (optional)

Instruments

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

03.647.963 Insertion Device for Zero-P VA

Optional Instruments

03.647.980 Implant Holder for Zero-P VA

03.617.905 Shaft for angled Screwdriver, with Quick Coupling

03.647.903 Handle, small, with Quick Coupling

If necessary use the angled screwdriver to advance each screw another $\frac{1}{4}$ – $\frac{1}{2}$ turn. This tightening step lags the stops of the interbody plate to the anterior surface of the vertebral bodies and increases the apposition of the implant to the vertebral body endplates.

Note: When tightening screws, the insertion device or implant holder should be used to minimize implant movement.

Precaution: Do not continue advancing any screw after the stops of the interbody plate are lagged to the anterior surface of the vertebral bodies and do not advance any screw more than $\frac{1}{2}$ turn during tightening. Over-tightening may strip bone and compromise fixation of the implant in vertebral bodies.



Implant Removal

If a ZERO-P VA Implant must be removed, the following technique is recommended.

1. Remove screws

Instruments

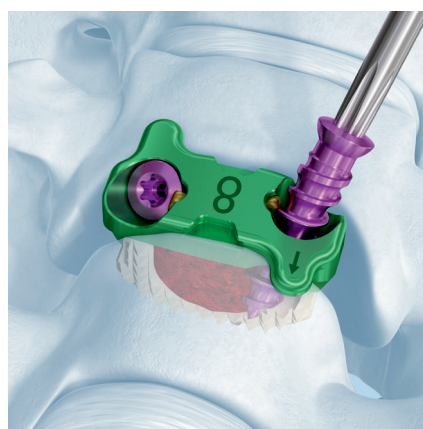
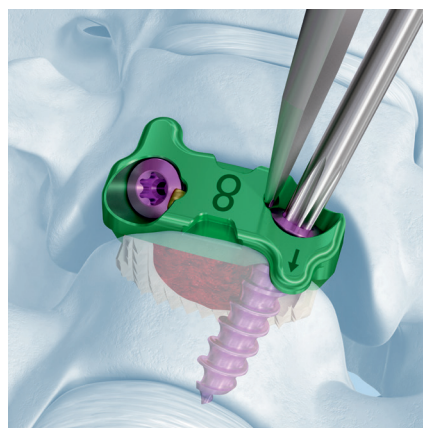
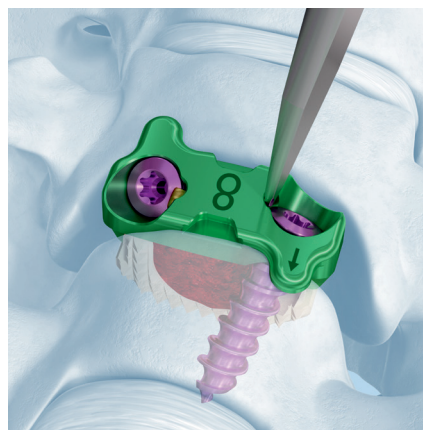
03.617.902 Screwdriver Shaft Stardrive, T8, self-holding

03.647.903 Handle, small, with Quick Coupling

03.647.985 Screw Removal Blade

Engage the tip of the screw removal blade with the blocking mechanism of the plate corresponding to the screw to be removed. Attach the handle to the screwdriver shaft, then engage the assembled driver into the first screw to be removed. While pressing the blocking mechanism toward the midline with the removal blade, turn the assembled driver counterclockwise to remove the screw.

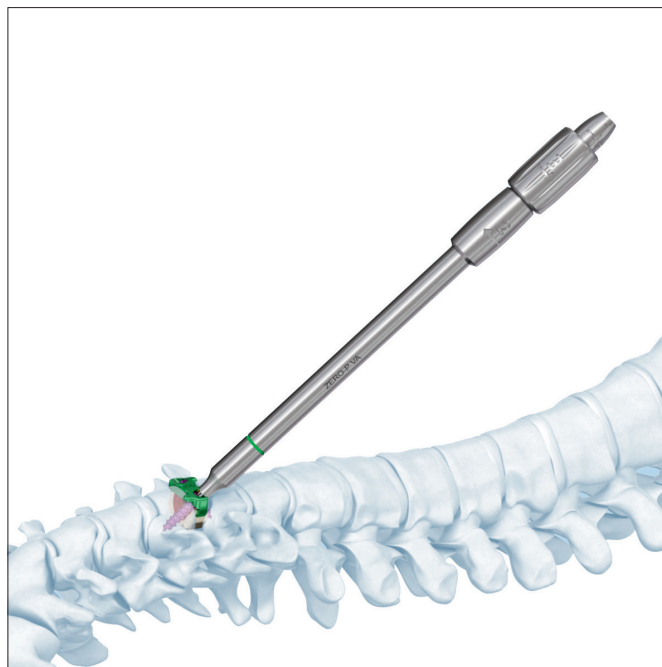
Repeat this step with the other screw.



Alternative technique: Screw removal

Instrument

03.647.971 Screw Removal Screwdriver

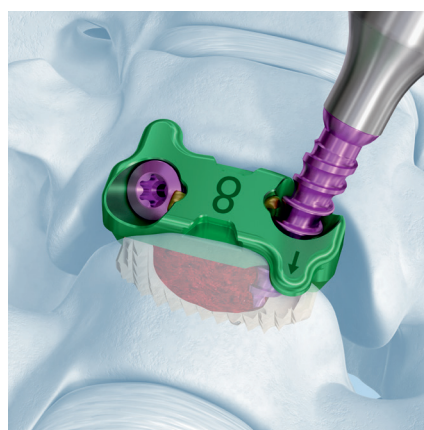
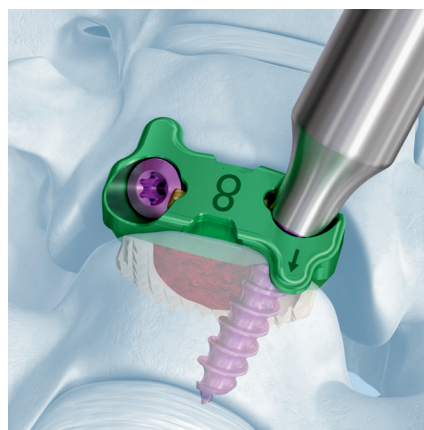
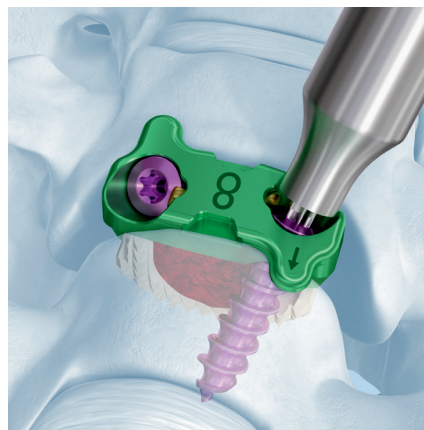


Engage the tip of the removal screwdriver in the drive recess of the first screw to be removed. Turn the top knob of the removal driver counterclockwise to fully engage the inner shaft into the screw. Lower the outer sleeve of the removal driver by turning clockwise until the sleeve retracts the blocking mechanism in the interbody plate. Finally, turn the middle section counterclockwise to remove the screw.

Repeat this step with the second screw.

Precautions:

- If the inner shaft is not fully engaged or the outer sleeve not fully seated prior to attempting subsequent screw removal technique steps, breakage of the driver may occur and could potentially harm the patient.
- The removal screwdriver should only be used for screw removal; use of the removal screwdriver for screw insertion may lead to driver and/or implant breakage.



2. Extract Implant

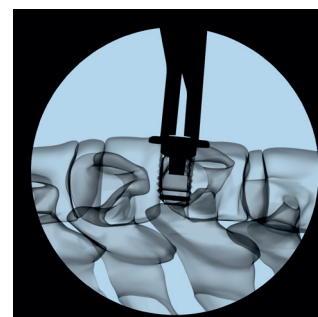
Instrument

03.647.963 Insertion Device for Zero-P VA

Optional Instrument

03.647.980 Implant Holder for Zero-P VA

Once the screws are removed, remove the ZERO-P VA Implant using the insertion device. Engage the insertion device to the implant by first aligning the recessed grooves located midline on the anterior face of the implant with the pronged tabs of the device tip.



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.depuysynthes.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.

