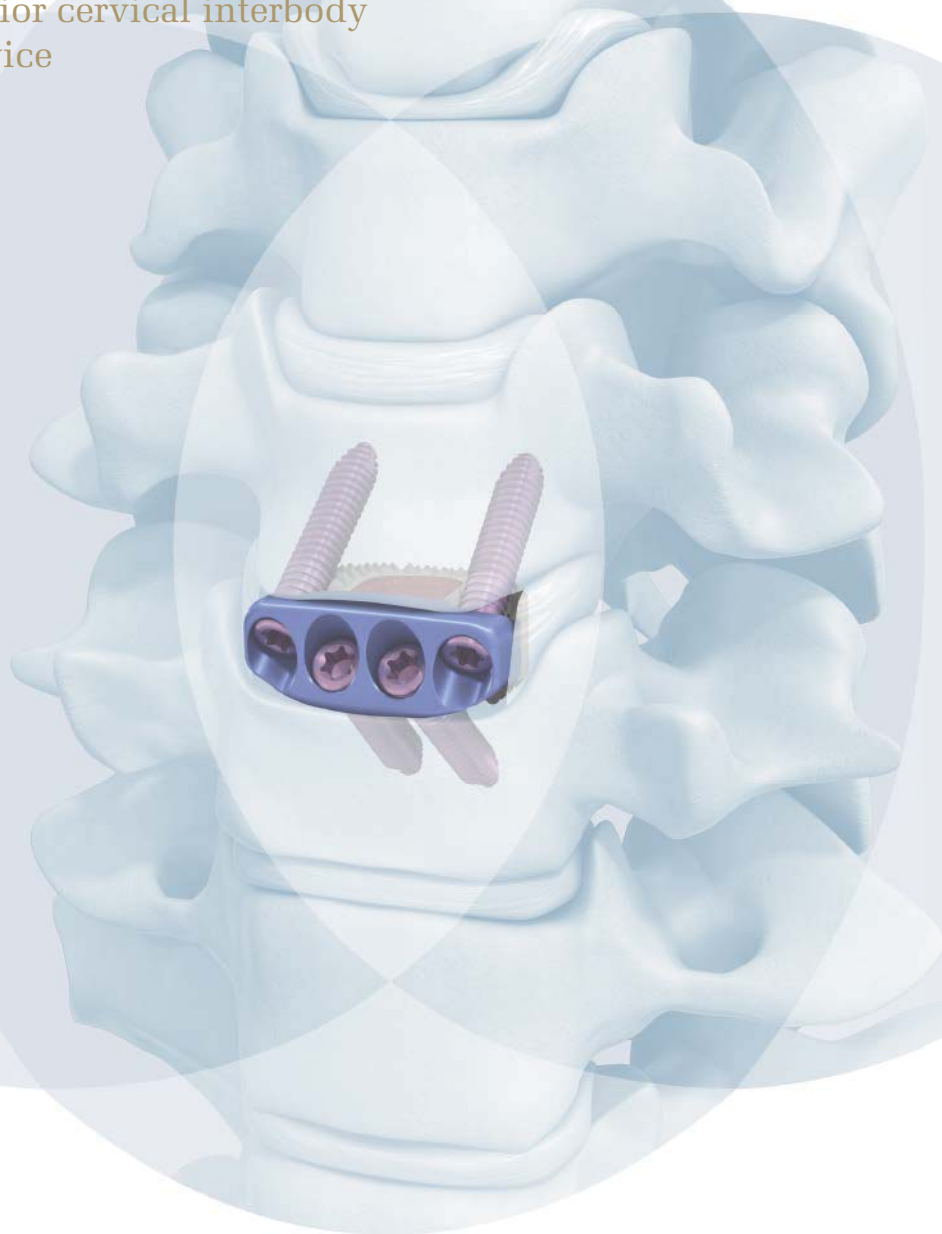


# ZERO-P® STAND ALONE SPACER

Zero-Profile anterior cervical interbody fusion (ACIF) device





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# ZERO-P SPACER INSTRUMENTS AND IMPLANTS

Zero-Profile anterior cervical interbody fusion (ACIF) device

## STAND ALONE ACIF IMPLANT

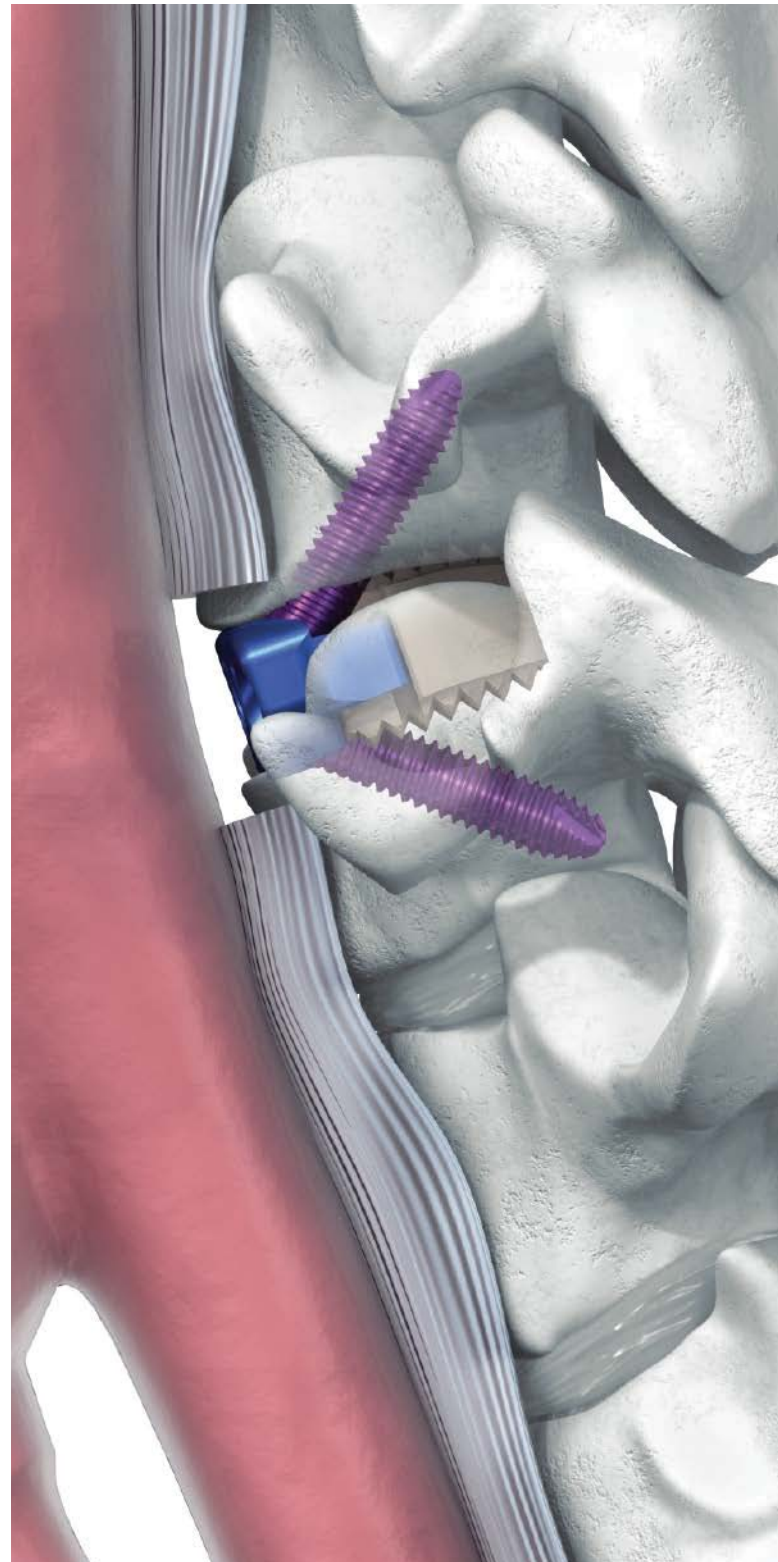
The ZERO-P Spacer is a stand alone implant for use in cervical interbody fusion, which combines the functionality of a cervical interbody spacer with the benefits of an anterior cervical plate.<sup>1-4</sup>

### Zero Profile

- **Designed to minimize contact with local anatomical structures.** The ZERO-P Spacer does not extend beyond the confines of the intervertebral disc space, limiting the risk of damage to vessels and adjacent soft tissues. In addition, preparation of the anterior surface of the vertebral body is not necessary, because the implant does not lie against the vertebral body anterior surface.
- **Designed to prevent contact with adjacent levels.** Cervical plates placed near the adjacent level discs may contribute to bone formation near or around the adjacent level, which may lead to future complications.<sup>5</sup>

### Ease of Use

- Because the plate and spacer are preassembled, the plate is automatically aligned upon implant insertion. This avoids the process of aligning and realigning an anterior cervical plate.
- The ZERO-P Spacer Screws have a one-step locking conical head which locks the screw to the plate by simply inserting and tightening the screw.
- The ZERO-P Spacer may be used to facilitate surgeries where ZERO-P is implanted adjacent to a prior fusion.





**PEEK Interbody Spacer**

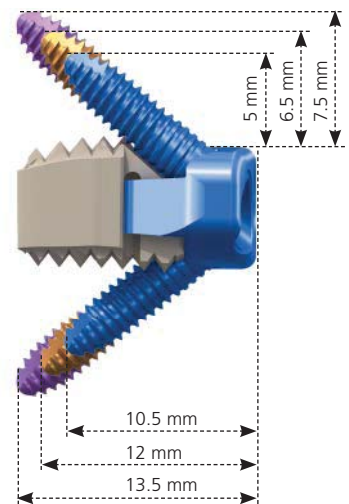
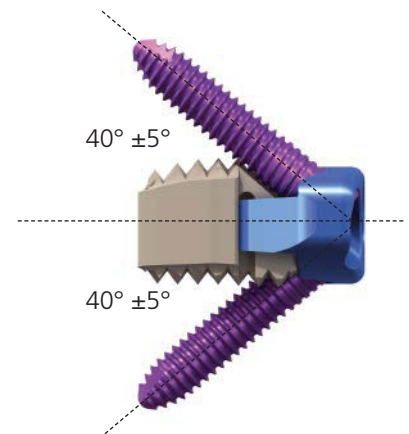
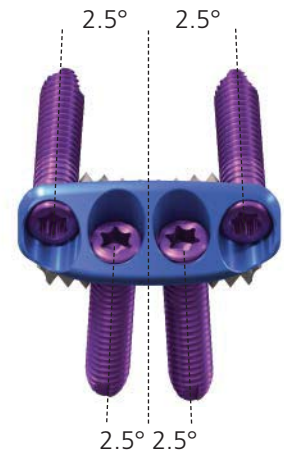
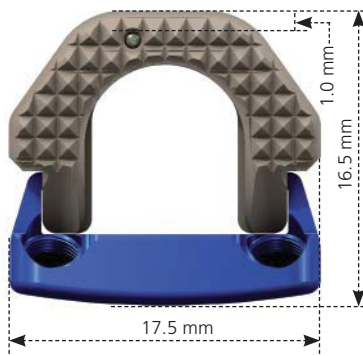
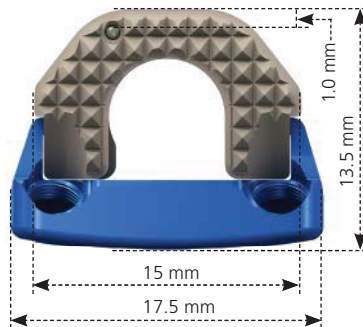
- Radiopaque marker for posterior visualization during imaging
- Spacer component is made of pure medical grade PEEK-OPTIMA (polyetheretherketone)
- Teeth on the superior and inferior implant surfaces provide initial stability

**Titanium Alloy Plate**

- Provides a secure, rigid screw locking interface
- Stresses in the plate are decoupled from the spacer through an innovative interface

**Locking Head Screws**

- Screws form a bone wedge with a  $40^\circ \pm 5^\circ$  cranial/caudal angle and  $2.5^\circ$  medial/lateral angle
- One-step locking screws
- Self-tapping screw improves thread purchase
- Trilobular thread-cutting flutes are self-centering



# AO PRINCIPLES

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In 1958, the AO formulated four basic principles, which have become the guidelines for internal fixation.<sup>6</sup> They are:

- Anatomic reduction
- Stable 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.<sup>6</sup>

# INDICATIONS AND CONTRAINDICATIONS

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## **Indications**

The *DePuy Synthes Spine ZERO-P Spacer* is a stand alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2 to T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of nonoperative treatment. The interior of the spacer component of the *DePuy Synthes Spine ZERO-P Spacer* should be packed with autogenous bone graft and implanted via an anterior approach.

## **Contraindications**

1. Use of the *DePuy Synthes Spine ZERO-P Spacer* is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.
3. Severe obesity or degenerative diseases are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
4. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions. These patients may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
5. Prior fusion at the level to be treated.
6. Any condition not described in the Indications for Use.

**Please refer to product insert for complete system description, indications, and warnings.**

# PREOPERATIVE PLANNING

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Determine the surgical approach and estimate the appropriate ZERO-P Spacer size.

**Notes:** With the segment fully distracted, the ZERO-P Spacer must fit firmly between the end plates before locking head screws are inserted. When rocking the aiming device backward and forward in a cranial to caudal direction, no toggling of the implant should be evident.

It is recommended to select the maximum implant size in order to optimize the stability of the segment through tension in the annulus fibrosus and longitudinal ligaments.



# CONSIDERATIONS FOR USE ADJACENT TO A PRIOR FUSION

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

**Caution:** Placement of the ZERO-P Spacer adjacent to a previous, multi-level fusion could result in increased loading. Supplemental fixation should be considered in cases where the ZERO-P Spacer is placed adjacent to a previous, multi-level fusion.

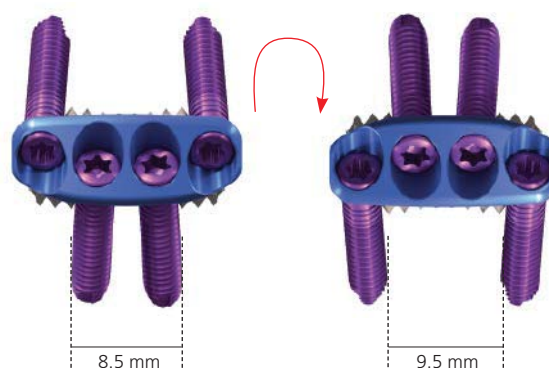
Do not place the ZERO-P Spacer adjacent to previously implanted hardware if the adjacent level cannot be confirmed to be fused or where fusion has not occurred.



**Important:** 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 Spacer with lordotic and parallel sagittal profiles with either the medial screws facing cranially or caudally. Consider screw dimensions to determine desired orientation.

**Caution:** Do not orient the ZERO-P Spacer 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:**

1. If adjacent hardware prevents less than 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.
2. 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.
3. Confirm that the ZERO-P Spacer is not placed in direct contact with implanted hardware associated with the previously fused level. If the ZERO-P Spacer remains in direct contact with hardware associated with the previously fused level, increased loading may be placed on the ZERO-P Spacer leading to potential postoperative device failure and potential harm to the patient.

# IMPLANT INSERTION

## 1

### Approach

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

## 2

### Determine Appropriate Implant

#### Instruments

03.617.720– 03.617.729	ZERO-P Trial Spacer, parallel, heights 5–12 mm, purple
03.617.730– 03.617.739	ZERO-P Trial Spacer, parallel, large, heights 5–12 mm, purple
03.617.750– 03.617.759	ZERO-P Trial Spacer, lordotic, heights 5–12 mm, blue
03.617.760– 03.617.769	ZERO-P Trial Spacer, lordotic, large, heights 5–12 mm, blue
03.617.780– 03.617.789	ZERO-P Trial Spacer, convex, heights 5–12 mm, gold
03.617.790– 03.617.799	ZERO-P Trial Spacer, convex, large heights 5–12 mm, gold

#### Optional Instruments

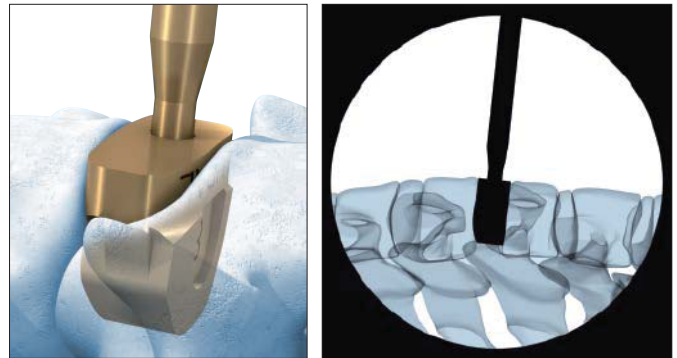
03.617.940	Handle, with large quick coupling
03.820.113	Slotted Mallet

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



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

- ⓘ **Caution:** 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 must fit tightly and accurately 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.



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 spacers.

**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 Spacer.

To minimize potential increased risk to the patient, it is recommended to:

- Trial with shorter height trial spacers before trialing with taller height trial spacers; and
- Trial with the standard footprint size trial spacers before trialing with large footprint size trial spacers.

### 3

#### Pack Implant with Autogenous Bone Graft

##### Instruments

03.617.970 Cancellous Bone Impactor

03.617.984 Packing Block

Place the appropriate ZERO-P Spacer into the packing block.

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

##### Notes:

**To ensure optimal contact with the vertebral end plates, it is important to fill the implant until the graft material protrudes from the perforations in the spacer.**

**The bone impactor can only be used with the standard size footprints of the ZERO-P Spacer.**



### 4

#### Insert Implant

##### Instrument

03.617.963 Aiming Device

##### Optional Instruments

03.617.980 Implant Holder

03.617.981 Impactor, flat

03.617.982 Impactor, ball tip

03.820.113 Slotted Mallet

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.

- ⚠ **Caution:** 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.

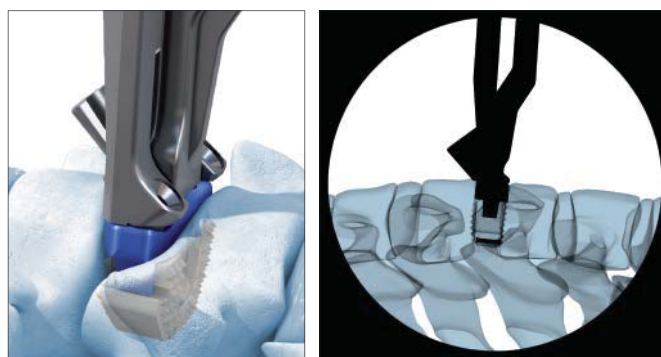
#### Using the Implant Holder

Alternatively, the implant can be inserted into the disc space with the forceps-style 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 and/or ball tip impactor.

- ⚠ **Important:** Verify final implant position relative to the vertebral bodies in the AP and lateral direction with the help of intraoperative imaging. The PEEK spacer has a single posterior x-ray marker incorporated into the implant to enable accurate intraoperative radiographic assessment of the implant position.

**Notes:** The convex shaped spacers must be oriented with the medial screws pointing caudally.

The parallel and lordotic spacers can be oriented in either direction (medial screws pointing cranially or caudally). In order to facilitate placement of the device, the recommendation is to first attempt orientation of the implant with the medial screws pointing caudally [for convex shaped spacers this is the only orientation possible]. If implantation is compromised in this orientation, orient the implant in the other direction (medial screws pointing cranially).



# 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

03.617.903	Handle with Quick Coupling, small
03.617.912	2.0 mm Drill Bit with 12 mm stop, quick coupling
03.617.914	2.0 mm Drill Bit with 14 mm stop, quick coupling
03.617.916	2.0 mm Drill Bit with 16 mm stop, quick coupling
03.617.963	Aiming Device

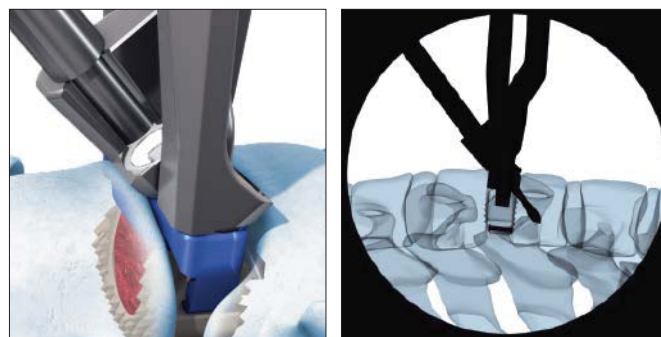
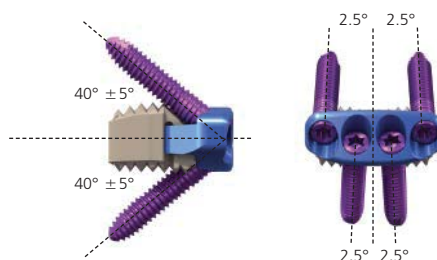
Select a drill bit of appropriate stop depth. Insert the drill bit into the drill and screw hole of the aiming device and drill until the stop on the drill contacts the guide.

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

Remove the drill bit.

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

**Caution:** When using the drill bit in combination with the aiming device, take care to apply only axial forces to the drill. Bending forces applied when the tip of the drill is engaged in the aiming device can lead to the drill breaking and potentially increased risk to the patient.





## A2

### Insert First Screw

#### Instruments

03.110.002.99 Torque Limiting Attachment, 1.2 Nm

03.617.902 StarDrive Screwdriver Shaft, T8, self-retaining

03.617.903 Handle with Quick Coupling, small

#### Optional Instrument

03.617.901 Holding Sleeve, for StarDrive Screwdriver Shaft

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

Assemble the torque limiting attachment to the screwdriver shaft and handle.

**Caution:** The torque limiting attachment must be used. If the torque limiting attachment is not used, breakage of the driver may occur, potentially increasing risk to the patient.

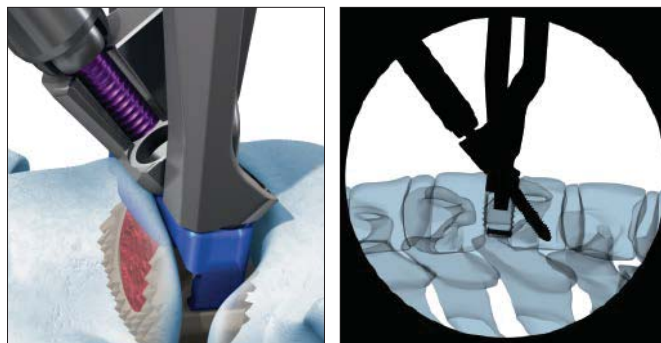
Load a screw onto the screwdriver with torque limiting attachment. The screw will self-retain to the screwdriver, however, the holding sleeve may be used for increased screw retention.

**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.

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

ⓘ **Caution:** The screws should be tightened only after all screws have been inserted.





## A3

### Drill Remaining Pilot Holes

#### Instruments

03.617.903	Handle with Quick Coupling, small
03.617.912	2.0 mm Drill Bit with 12 mm stop, quick coupling
03.617.914	2.0 mm Drill Bit with 14 mm stop, quick coupling
03.617.916	2.0 mm Drill Bit with 16 mm stop, quick coupling
03.617.963	Aiming Device

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

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

Remove the drill bit.

Repeat for the remaining screw holes.

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

**Caution:** When using the drill bit in combination with the aiming device, take care to apply only axial forces to the drill. Bending forces applied when the tip of the drill is engaged in the aiming device can lead to the drill breakage and potentially increased risk to the patient.



## A4

### Insert Remaining Screws

#### Instruments

03.110.002.99 Torque Limiting Attachment, 1.2 Nm

03.617.902 StarDrive Screwdriver Shaft, T8,  
self-retaining

03.617.903 Handle with Quick Coupling, small

#### Optional Instrument

03.617.901 Holding Sleeve, for StarDrive  
Screwdriver Shaft

Remove the aiming device from the implant.

Load the selected screw onto the screwdriver with torque limiting attachment. The screw will self-retain to the screwdriver, however, the holding sleeve may be used for increased screw retention.

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

Repeat for the remaining screws.

**Caution:** 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

03.110.002.99	Torque Limiting Attachment, 1.2 Nm
03.617.902	StarDrive Screwdriver Shaft, T8, self-retaining
03.617.903	Handle with Quick Coupling, small

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

**Caution:** If the torque limiting attachment is not used, breakage of the driver 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.



# OPTION B: DRILL GUIDE AND FREEHAND SCREW

If surgeon preference is to not use the aiming device, this alternative technique may be used.

## B1

### Drill First Pilot Hole

#### Instruments

03.617.903	Handle with Quick Coupling, small
03.617.912	2.0 mm Drill Bit with 12 mm stop, quick coupling
03.617.914	2.0 mm Drill Bit with 14 mm stop, quick coupling
03.617.916	2.0 mm Drill Bit with 16 mm stop, quick coupling
03.617.962	Drill Guide with Handle

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.

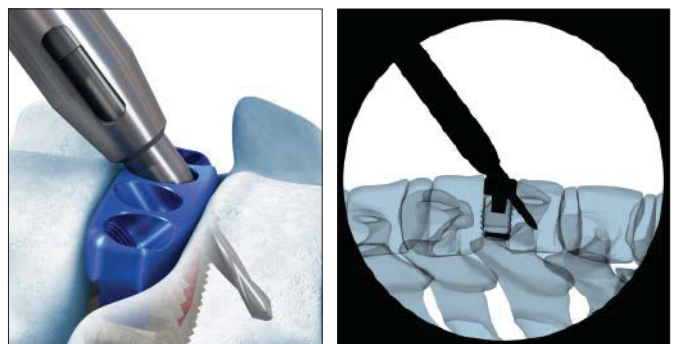
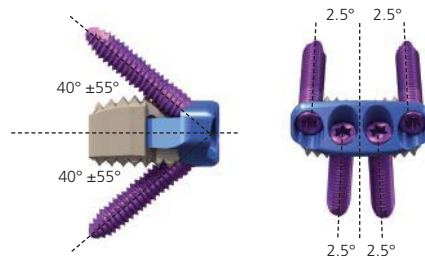
Insert the drill guide into the screw hole at the appropriate angle. The tip of the drill guide is designed to fit inside the screw hole of the plate and guide the correct angle.

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

Remove the drill bit and guide.

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

- Note:** The drill bits are each 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

03.110.002.99 Torque Limiting Attachment, 1.2 Nm

03.617.902 StarDrive Screwdriver Shaft, T8, self-retaining

03.617.903 Handle with Quick Coupling, small

#### Optional Instrument

03.617.901 Holding Sleeve, for StarDrive Screwdriver Shaft

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

Assemble the torque limiting attachment to the screwdriver shaft and handle.

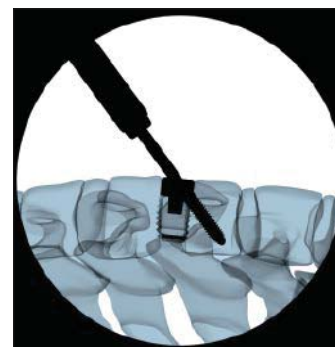
**Caution:** If the torque limiting attachment is not used, breakage of the driver may occur and could potentially increase risk to the patient.

Load the screw onto the self-retaining screwdriver with torque limiting attachment. The screw will self-retain to the screwdriver, however, the holding sleeve may be used for increased screw retention.

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

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

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



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## B3

### Insert Remaining Screws

Repeat Steps B1 and B2 for the remaining screws.

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## B4

### Tighten Screws

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#### Instruments

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03.110.002.99	Torque Limiting Attachment, 1.2 Nm
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03.617.902	StarDrive Screwdriver Shaft, T8, self-retaining
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03.617.903	Handle with Quick Coupling, small
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To lock the screwhead in the plate, always use the torque limiting attachment with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

**Caution:** If the torque limiting attachment is not used, breakage of the driver may occur and could potentially increase risk to 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.





# OPTION C: THREADED DRILL GUIDE AND FREEHAND SCREW

## C1

### Drill First Pilot Hole

#### Instruments

03.617.903	Handle with Quick Coupling, small
03.617.912	2.0 mm Drill Bit with 12 mm Stop, quick coupling
03.617.914	2.0 mm Drill Bit with 14 mm Stop, quick coupling
03.617.916	2.0 mm Drill Bit with 16 mm Stop, quick coupling
03.617.968	Threaded Drill Guide

Determine the trajectory for the threaded drill guide. The correct angulations 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.

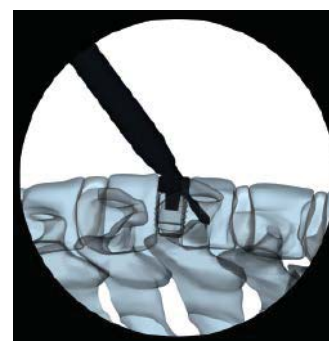
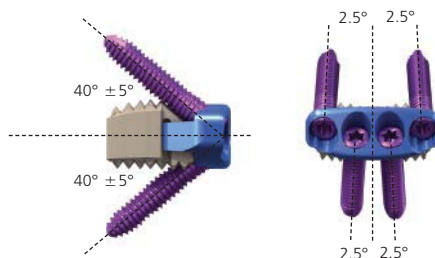
Insert the threaded drill guide into the screw hole at the appropriate angle. The tip of the drill guide fits into the screw hole of the interbody plate to produce the correct angle.

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

Remove the drill bit and the threaded drill guide.

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

**Note:** The drill bits are each 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

03.110.002.99	Torque Limiting Attachment, 1.2 Nm
03.617.901	Holding Sleeve, for StarDrive Screwdriver Shaft
03.617.902	StarDrive Screwdriver Shaft , T8, self-retaining
03.617.903	Handle with Quick Coupling, small

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

Assemble the torque limiting attachment to the screwdriver shaft and handle.

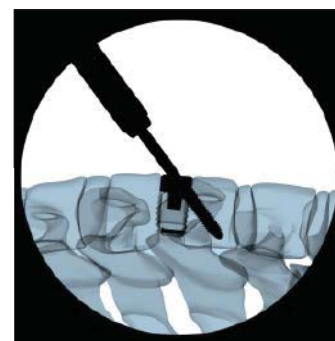
**Caution: If the torque limiting attachment is not used, breakage of the screwdriver may occur and could potentially harm the patient.**

Load the screw onto the self-retaining screwdriver with the torque limiting attachment. The screw will self-retain to the screwdriver, however, the holding sleeve may be used for increased screw retention.

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

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

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





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## C3

### Insert Remaining Screws

Repeat Steps C1 and C2 for the remaining screws.

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## C4

### Tighten Screws

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#### Instruments

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03.110.002.99	Torque Limiting Attachment, 1.2 Nm
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03.617.902	StarDrive Screwdriver Shaft , T8, self-retaining
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03.617.903	Handle with Quick Coupling, small
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To lock the screwhead in the plate, always use the torque limiting attachment with the screwdriver to tighten each screw to the recommended 1.2 Nm torque.

**Caution:** If the torque limiting attachment is not used, breakage of the screwdriver may occur and could potentially increase risk to 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.



# 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 2.0 mm Awl with Sleeve

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

**Note:** Lateral screws should always point medially.

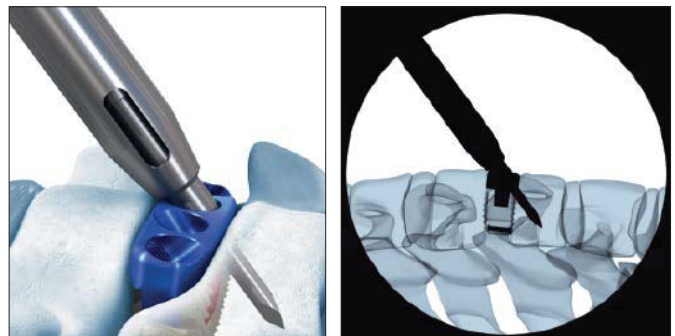
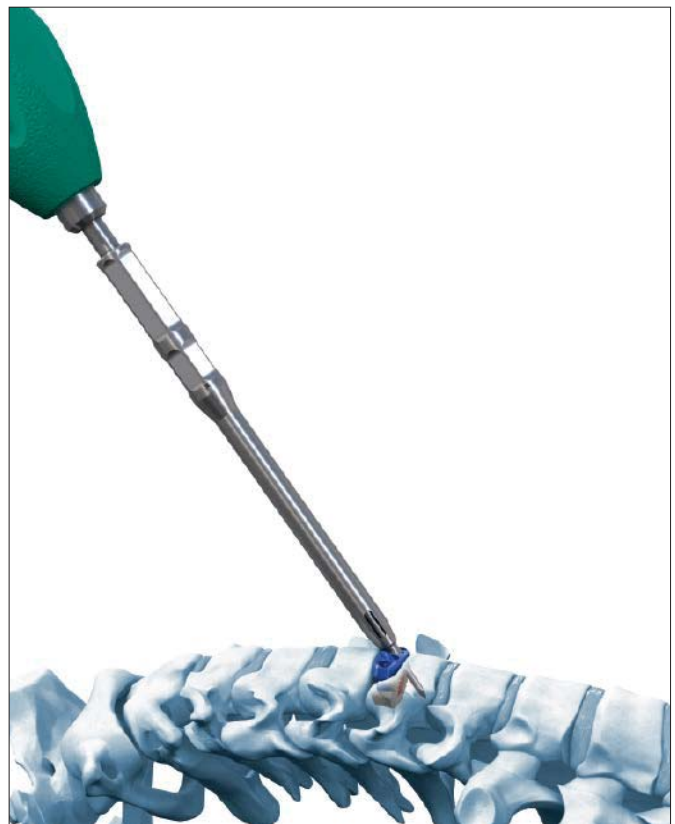
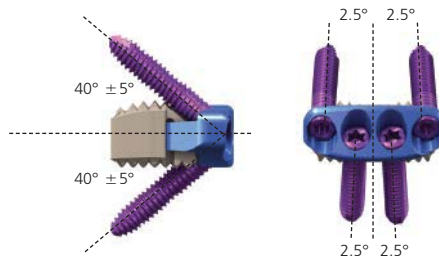
Insert the awl at the appropriate angle into a screw hole in the plate and push down, while simultaneously twisting the handle.

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

- ❶ **Important:** 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.

**Caution:** 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

03.110.002.99 Torque Limiting Attachment, 1.2 Nm

03.617.902 StarDrive Screwdriver Shaft, T8, self-retaining

03.617.903 Handle with Quick Coupling, small

#### Optional Instrument

03.617.901 Holding Sleeve, for StarDrive Screwdriver Shaft

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

Assemble the torque limiting attachment to the screwdriver shaft and handle.

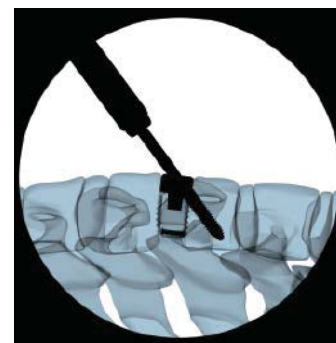
**Caution:** If the torque limiting attachment is not used, breakage of the driver may occur and could potentially increase risk to the patient.

Load the screw onto the self-retaining screwdriver with torque limiting attachment. The screw will self-retain to the screwdriver, however, the holding sleeve may be used for increased screw retention.

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

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

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



---

## D3

### Insert Remaining Screws

Repeat Steps D1 and D2 for the remaining screws.

---

## D4

### Tighten Screws

---

#### Instruments

03.110.002.99	Torque Limiting Attachment, 1.2 Nm
03.617.902	StarDrive Screwdriver Shaft, T8, self-retaining
03.617.903	Handle with Quick Coupling, small

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

**Caution:** If the torque limiting attachment is not used, breakage of the driver may occur and could potentially increase risk to 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.



## OPTION E: ANGLED INSTRUMENTS

If patient anatomy does not allow use of the straight instruments, the angled awl and angled screwdriver may be used.

### E1

#### Awl First Pilot Hole

##### Instrument

03.617.993 2.0 mm Angled Awl

03.820.113 Slotted Mallet

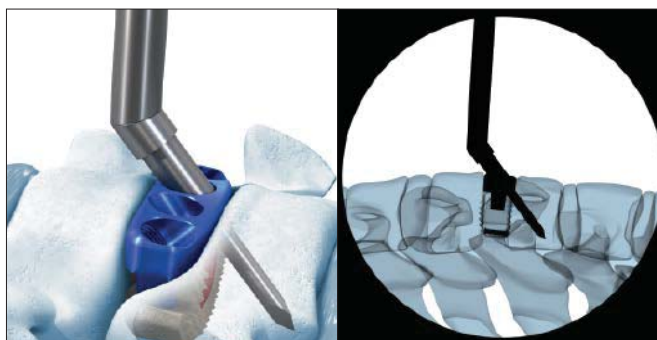
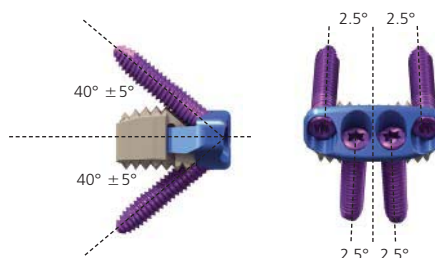
Determine the entry point and trajectory for the screw. The correct angulations for the screws are  $40^\circ$  in the caudal or cranial direction. The medial screws point  $2.5^\circ$  laterally and the lateral screws point  $2.5^\circ$  medially.

**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 slotted mallet until the awl is seated.

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

- ❶ **Important:** Intraoperative imaging should be used to verify awl position.



## E2

### Insert First Screw

#### Instrument

03.617.900 Angled StarDrive Screwdriver, T8, with Sleeve, self-retaining

#### Optional Instruments

03.617.972 Sleeve for Angled StarDrive Screwdriver T8/Locking

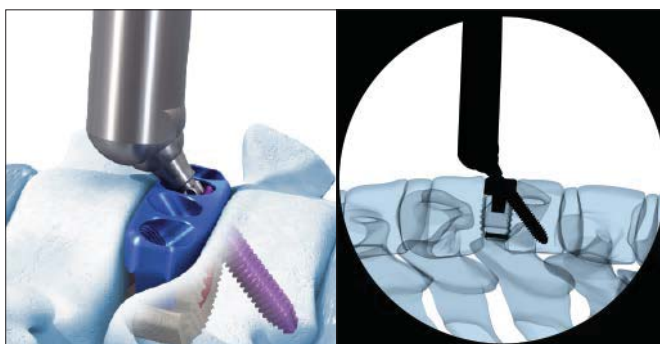
03.617.905 Inner Shaft for Angled Screwdriver

03.617.903 Handle with Quick Coupling, small

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.

**Important:** 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

03.110.002.99	Torque Limiting Attachment, 1.2 Nm
03.617.902	StarDrive Screwdriver Shaft, T8, self-retaining
03.617.903	Handle with Quick Coupling, small

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#### Optional Instruments

03.617.972	Sleeve for Angled StarDrive Screwdriver, T8/Locking
03.617.905	Inner Shaft for Angled Screwdriver
03.110.005	Handle for Torque Limiting Attachment

To lock the screwhead in the plate, always use the torque limiting attachment with the straight screwdriver or the optional locking angled screwdriver construct to tighten each screw to the recommended 1.2 Nm torque.

**Caution:** If the torque limiting attachment is not used, breakage of the driver may occur and could potentially increase risk to 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 Spacer must be removed, the following technique is recommended.

## 1

### Remove Screw

#### Instruments

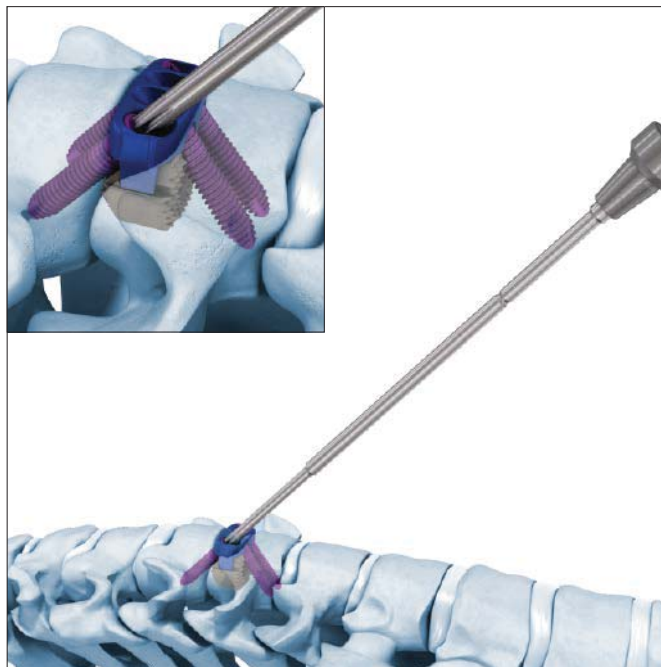
03.617.902 Stardrive Screwdriver Shaft, T8, self-retaining, quick coupling

03.617.903 Handle with Quick Coupling, small

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 Spacer. 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 ensures the implant will be properly secured during removal.

**Note:** Torque limiting attachment should not be used with driver to remove screws.





## OPTIONAL TECHNIQUE

### 1a

#### Remove Screw with Conical Extraction Screw

##### Instruments

03.617.9715	Conical Extraction Screw, sterile
03.617.9755	2.0 mm Drill Bit, Quick Coupling, sterile, for Conical Extraction Screw

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.

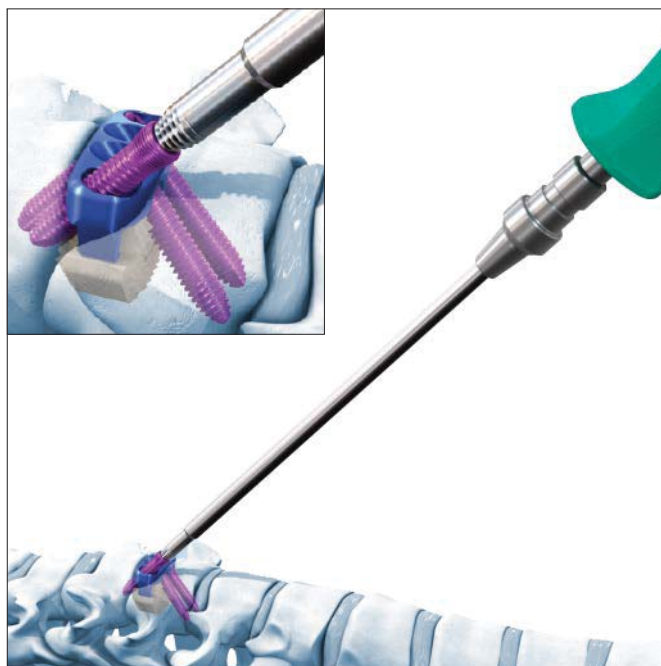
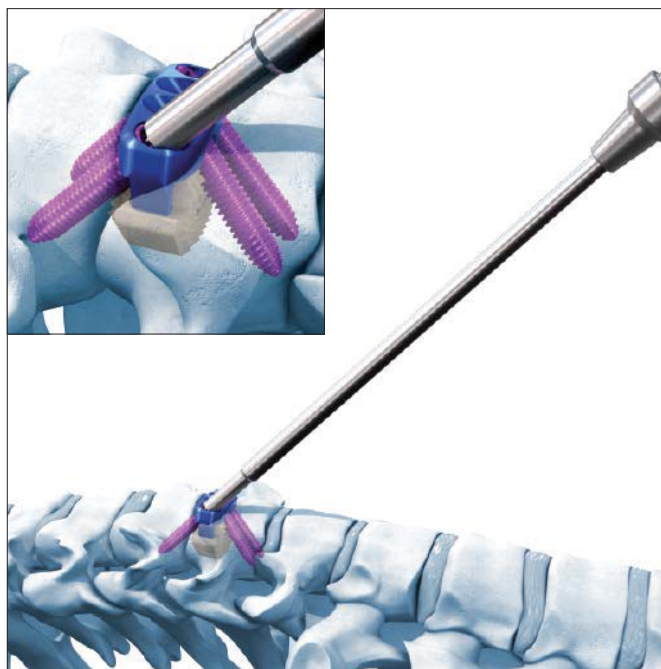
**Warning:** Drilling into the screw recess with the 2.0 mm drill bit will cause metal debris. Use of suction and irrigation is recommended to remove the debris from the wound.

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.

**Caution:** 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.

**Caution:** 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. Multiple screws in the same removal procedure may be removed with a single new 2.0 mm drill bit.



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## 2

### Extract Implant

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#### Instrument

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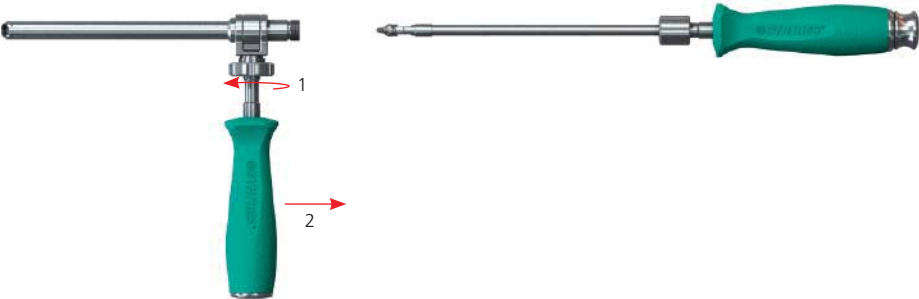
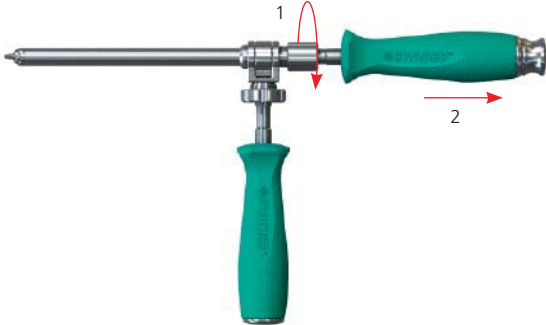
Once all screws are removed, the ZERO-P Spacer may be removed using the aiming device. Attach the aiming device to the implant by aligning the screw holes of the implant with the retention features on the aiming device and then expanding the aiming device.

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

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

# INSTRUMENT DISASSEMBLY

Angled StarDrive Screwdriver, T8, with Sleeve, self-retaining (03.617.900)



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**Holding Sleeve for StarDrive Screwdriver Shaft (03.617.901)**



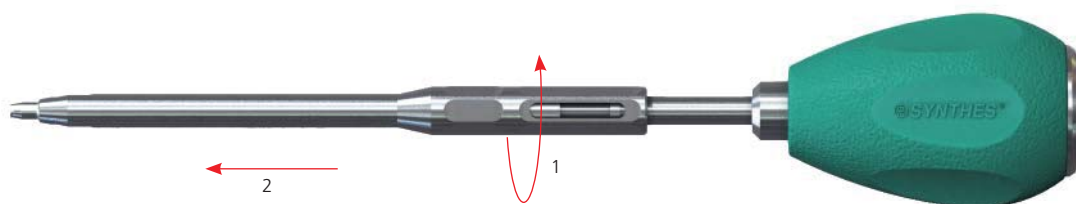
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**Handle with Quick Coupling, small (03.617.903)**



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**2.0 mm Awl with Sleeve (03.617.990)**









# IMPLANTS

## ZERO-P Spacers

- Supplied sterile and preassembled (spacer with anterior fixation plate)
- Available in 3 different shapes: convex, lordotic, and parallel
- Spacer component: PEEK-OPTIMA  
Plate component: Titanium alloy (Ti-6Al-7Nb)  
Marker: Titanium alloy (Ti-6Al-4V)

## ZERO-P Spacers, sterile

	Convex		Lordotic		Parallel	
						
Height	Standard	Large	Standard	Large	Standard	Large
5 mm	04.617.135S	04.617.235S*	04.617.125S	04.617.225S*	04.617.115S	04.617.215S*
6 mm	04.617.136S	04.617.236S	04.617.126S	04.617.226S	04.617.116S	04.617.216S
7 mm	04.617.137S	04.617.237S	04.617.127S	04.617.227S	04.617.117S	04.617.217S
8 mm	04.617.138S	04.617.238S	04.617.128S	04.617.228S	04.617.118S	04.617.218S
9 mm	04.617.139S	04.617.239S	04.617.129S	04.617.229S	04.617.119S	04.617.219S
10 mm	04.617.130S	04.617.230S	04.617.120S	04.617.220S	04.617.110S	04.617.210S
11 mm	04.617.131S	04.617.231S	04.617.121S	04.617.221S	04.617.111S	04.617.211S
12 mm	04.617.132S	04.617.232S*	04.617.122S	04.617.222S*	04.617.112S	04.617.212S*

## 3.0 mm Titanium Cervical Spine Locking Screws

- Self-tapping
- Self-centering
- Titanium alloy (Ti-6Al-7Nb)
- Color-coded by screw length



	Length	Color
04.617.812	12 mm	Blue
04.617.814	14 mm	Gold
04.617.816	16 mm	Purple

Note: Screws are provided nonsterile unless otherwise indicated. For sterile screws, see additionally available implants.

\*Also available.

# INSTRUMENTS

03.110.002.99 Torque Limiting Attachment, 1.2 Nm



03.617.720–  
03.617.729 ZERO-P Trial Spacers, parallel,  
5 mm–12 mm heights



03.617.730†–  
03.617.739 ZERO-P Trial Spacers, large, parallel,  
5 mm–12 mm heights



03.617.750–  
03.617.759 ZERO-P Trial Spacers, lordotic,  
5 mm–12 mm heights



03.617.760†–  
03.617.769 ZERO-P Trial Spacers, large, lordotic,  
5 mm–12 mm heights



03.617.780–  
03.617.789 ZERO-P Trial Spacers, convex,  
5 mm–12 mm heights



03.617.790†–  
03.617.799 ZERO-P Trial Spacers, large, convex,  
5 mm–12 mm heights



03.617.900 Angled StarDrive Screwdriver, T8, with  
Sleeve, self-retaining



03.617.901 Holding Sleeve, for StarDrive Screwdriver  
Shaft



03.617.902 StarDrive Screwdriver Shaft, T8,  
self-retaining



† 5 mm and 12 mm heights are also available.

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03.617.903 Handle with Quick Coupling, small



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03.617.912 2.0 mm Drill Bits, quick coupling  
with 12 mm stop  
03.617.914 with 14 mm stop  
03.617.916 with 16 mm stop



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03.617.940 Handle, with large quick coupling



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03.617.962 Drill Guide with handle



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03.617.963 Aiming Device



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03.617.970 Cancellous Bone Impactor





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03.617.980 Implant Holder



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03.617.981 Impactor, flat



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03.617.982 Impactor, ball tip



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03.617.984 Packing Block, for ZERO-P Spacers



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03.617.990 2.0 mm Awl, with sleeve



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03.617.993 2.0 mm Angled Awl



---

03.820.113 Slotted Mallet



# ZERO-P SPACER AND TITANIUM SCREW SET (01.617.900)

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## Graphic Case

60.617.900 Graphic Case, for ZERO-P Spacer and Implant Set

## Module

60.617.902 Module, for Trial Implants

## Implants

3.0 mm Titanium Cervical Spine Locking Screws, 10 ea

04.617.812 12 mm

04.617.814 14 mm

04.617.816 16 mm

## Instruments

03.110.002.99 Torque Limiting Attachment, 1.2 Nm  
 03.617.900 Angled StarDrive Screwdriver, T8, with Sleeve, self-retaining  
 03.617.901 Holding Sleeve, for StarDrive Screwdriver Shaft  
 03.617.902 StarDrive Screwdriver Shaft, T8, self-retaining, quick coupling, 2 ea  
 03.617.903 Handle with Quick Coupling small, 2 ea  
 03.617.912 2.0 mm Drill Bit with 12 mm Stop, quick coupling, 2 ea  
 03.617.914 2.0 mm Drill Bit with 14 mm Stop, quick coupling, 2 ea  
 03.617.916 2.0 mm Drill Bit with 16 mm Stop, quick coupling, 2 ea  
 03.617.940 Handle, with large quick coupling  
 03.617.962 Drill Guide with Handle  
 03.617.963 Aiming Device  
 03.617.970 Cancellous Bone Impactor  
 03.617.980 Implant Holder  
 03.617.981 Impactor, flat  
 03.617.982 Impactor, ball tip  
 03.617.984 Packing Block, for ZERO-P Spacers  
 03.617.990 2.0 mm Awl with Sleeve  
 03.617.993 2.0 mm Angled Awl  
 03.820.113 Slotted Mallet

For detailed cleaning and sterilization instructions, please refer to:

[www.synthes.com/cleaning-sterilization](http://www.synthes.com/cleaning-sterilization)

In Canada, the cleaning and sterilization instructions will be provided with the Loaner shipments.

# ZERO-P TRIAL SPACER SETS

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## **ZERO-P Parallel Trial Spacer Set (01.617.901)**

03.617.725	5 mm height
03.617.726	6 mm height
03.617.727	7 mm height
03.617.728	8 mm height
03.617.729	9 mm height
03.617.720	10 mm height
03.617.721	11 mm height
03.617.722	12 mm height
60.617.903	Trial Spacer Tray

## **ZERO-P Lordotic Trial Spacer Set (01.617.902)**

03.617.755	5 mm height
03.617.756	6 mm height
03.617.757	7 mm height
03.617.758	8 mm height
03.617.759	9 mm height
03.617.750	10 mm height
03.617.751	11 mm height
03.617.752	12 mm height
60.617.903	Trial Spacer Tray

## **ZERO-P Convex Trial Spacer Set (01.617.903)**

03.617.785	5 mm height
03.617.786	6 mm height
03.617.787	7 mm height
03.617.788	8 mm height
03.617.789	9 mm height
03.617.780	10 mm height
03.617.781	11 mm height
03.617.782	12 mm height
60.617.903	Trial Spacer Tray

## **ZERO-P Large Parallel Trial Spacer Set (01.617.056)**

03.617.736	6 mm height
03.617.737	7 mm height
03.617.738	8 mm height
03.617.739	9 mm height
03.617.730	10 mm height
03.617.731	11 mm height
60.617.903	Trial Spacer Tray

## **ZERO-P Large Lordotic Trial Spacer Set (01.617.057)**

03.617.766	6 mm height
03.617.767	7 mm height
03.617.768	8 mm height
03.617.769	9 mm height
03.617.760	10 mm height
03.617.761	11 mm height
60.617.903	Trial Spacer Tray

## **ZERO-P Large Convex Trial Spacer Set (01.617.058)**

03.617.796	6 mm height
03.617.797	7 mm height
03.617.798	8 mm height
03.617.799	9 mm height
03.617.790	10 mm height
03.617.791	11 mm height
60.617.903	Trial Spacer Tray

# ZERO-P IMPLANT SETS

---

## **ZERO-P Parallel Implant Set (01.617.910)**

with sterile implants

04.617.115S	5 mm height, 1 ea
04.617.116S	6 mm height, 2 ea
04.617.117S	7 mm height, 3 ea
04.617.118S	8 mm height, 3 ea
04.617.119S	9 mm height, 2 ea
04.617.110S	10 mm height, 1 ea
04.617.111S	11 mm height, 1 ea
04.617.112S	12 mm height, 1 ea
60.647.004	Carry Case for ZERO-P Spacers

## **ZERO-P Lordotic Implant Set (01.617.920)**

with sterile implants

04.617.125S	5 mm height, 1 ea
04.617.126S	6 mm height, 2 ea
04.617.127S	7 mm height, 3 ea
04.617.128S	8 mm height, 3 ea
04.617.129S	9 mm height, 2 ea
04.617.120S	10 mm height, 1 ea
04.617.121S	11 mm height, 1 ea
04.617.122S	12 mm height, 1 ea
60.647.004	Carry Case for ZERO-P Spacers

## **ZERO-P Convex Implant Set (01.617.930)**

with sterile implants

04.617.135S	5 mm height, 1 ea
04.617.136S	6 mm height, 2 ea
04.617.137S	7 mm height, 3 ea
04.617.138S	8 mm height, 3 ea
04.617.139S	9 mm height, 2 ea
04.617.130S	10 mm height, 1 ea
04.617.131S	11 mm height, 1 ea
04.617.132S	12 mm height, 1 ea
60.647.004	Carry Case for ZERO-P Spacers

## **ZERO-P Large Parallel Implant Set (01.617.050)**

with sterile implants

04.617.216S	6 mm height, 2 ea
04.617.217S	7 mm height, 3 ea
04.617.218S	8 mm height, 3 ea
04.617.219S	9 mm height, 2 ea
04.617.210S	10 mm height, 1 ea
04.617.211S	11 mm height, 1 ea
60.647.004	Carry Case for ZERO-P Spacers

## **ZERO-P Large Lordotic Implant Set (01.617.051)**

with sterile implants

04.617.226S	6 mm height, 2 ea
04.617.227S	7 mm height, 3 ea
04.617.228S	8 mm height, 3 ea
04.617.229S	9 mm height, 2 ea
04.617.220S	10 mm height, 1 ea
04.617.221S	11 mm height, 1 ea
60.647.004	Carry Case for ZERO-P Spacers

## **ZERO-P Large Convex Implant Set (01.617.052)**

with sterile implants

04.617.236S	6 mm height, 2 ea
04.617.237S	7 mm height, 3 ea
04.617.238S	8 mm height, 3 ea
04.617.239S	9 mm height, 2 ea
04.617.230S	10 mm height, 1 ea
04.617.231S	11 mm height, 1 ea
60.647.004	Carry Case for ZERO-P Spacers

## ALSO AVAILABLE

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314.467	StarDrive Screwdriver, T8, 105 mm
03.617.904	Screw Inserter, T8, self-retaining, quick coupling
03.617.930	Extension Shaft, 115 mm
03.617.941	Hex Adaptor, High Strength, quick coupling
03.617.968	Threaded Drill Guide, for ZERO-P
03.617.971S	Conical Extraction Screw, sterile
03.617.975S	2.0 mm Drill Bit, quick coupling, sterile, for Conical Extraction Screw
311.023	Ratcheting Screwdriver Handle
03.110.005	Handle for Torque Limiting Attachment
03.617.972	Sleeve for Angled Stardrive Screwdriver T8/Locking
03.617.905	Inner Shaft for Angled Screwdriver
	3.0 mm Titanium Cervical Spine Locking Screws, sterile (2/pkg)
04.617.812.02S	12 mm
04.617.814.02S	14 mm
04.617.816.02S	16 mm
	ZERO-P Trial Spacers, parallel, large
03.617.735	5 mm height
03.617.732	12 mm height
	ZERO-P Trial Spacers, lordotic, large
03.617.765	5 mm height
03.617.762	12 mm height
	ZERO-P Trial Spacers, convex, large
03.617.795	5 mm height
03.617.792	12 mm height
	ZERO-P Spacers, parallel, large, sterile
03.617.215S	5 mm height
03.617.212S	12 mm height
	ZERO-P Spacers, lordotic, large, sterile
04.617.225S	5 mm height
04.617.222S	12 mm height
	ZERO-P Spacers, convex, large, sterile
04.617.235S	5 mm height
04.617.232S	12 mm height
60.647.010	Label Sheet, for ZERO-P VA Trial Spacer Tray
60.807.050	Carry Case for ZERO-P Spacers

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- 
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