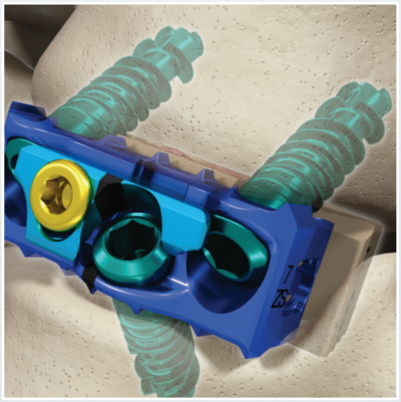
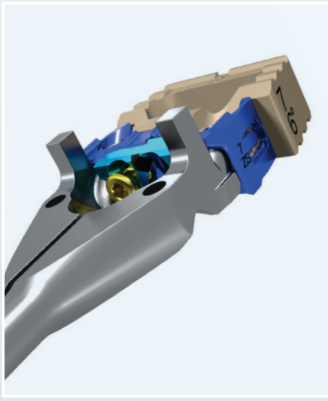
Optio-C®
Anterior Cervical PEEK
Interbody System

Surgical Technique Guide

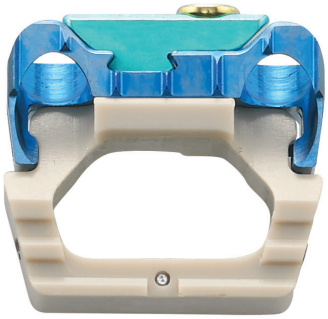


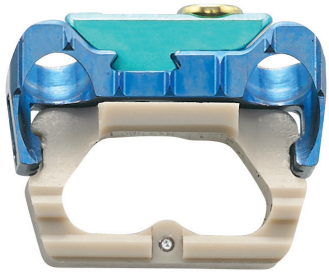



ZimVie

Optio-C®
Anterior Cervical PEEK
Interbody System

The Optio-C System provides a zero-profile cervical fusion option with a variety of materials, footprints, and geometries.





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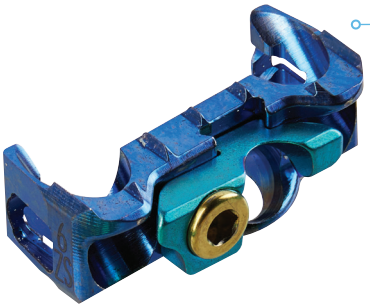
Global Availability: Some instruments and/or implants may not be available in some geographic regions. Check with local representation for product availability.

ZimVie Spine does not practice medicine. This technique was developed in conjunction with health care professionals. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Results will vary based on health, weight, activity and other variables. Not all patients are candidates for this product and/or procedure.

Optio-C System Overview

The Optio-C PEEK implant is composed of one Optio-C PEEK IBF spacer (PEEK spacer), one Optio-C anterior cervical plate, and three Optio-C bone screws. The Optio-C PEEK implant is used to provide structural stability in skeletally mature individuals following discectomy and is offered in multiple contours, lordotic angles, footprints, and heights to accommodate variations in cervical anatomy.

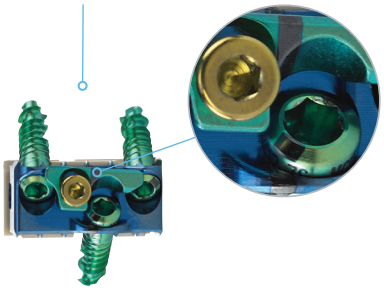


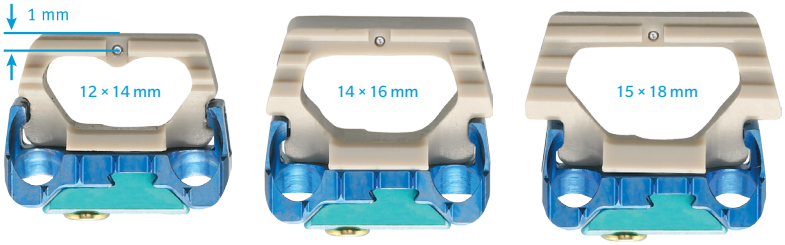
Optio-C Plate
(6–12 mm, 1 mm increments)
07.01873.006–012

Optio-C Plates

Optio-C plates are available in heights of 6 mm to 12 mm. All plates are 16 mm wide.

The Optio-C plate features a one-step screw locking mechanism designed to prevent screw migration. The plate midline is indicated by a black stripe on the anterior face of the plate.





Optio-C PEEK Spacers

Optio-C implants must be assembled before use as described in this document. The implants are provided in three footprints to meet varying patient anatomy: 12 × 14 mm, 14 × 16 mm, and 15 × 18 mm (depth x width including plate depth connected to PEEK spacer).

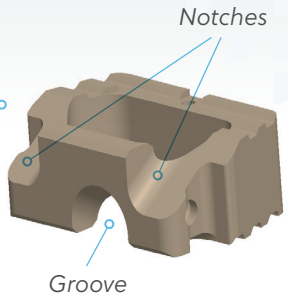
Optio-C System PEEK spacers are available in heights from 6 mm to 12 mm, in lordotic (6°) and parallel (0°). The height and lordosis are marked on the lateral sides of the PEEK spacer. A titanium alloy radiographic marker pin is located 1 mm from the posterior aspect of all Optio-C implants to help confirm implant positioning under fluoroscopy.

Lordotic

Parallel

All Optio-C System PEEK spacers have two notches and a groove to accommodate Optio-C System bone screws.

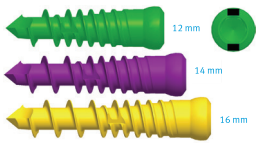
For the lordotic spacers, the anterior height is equal to the size specified, and the posterior height is approximately 1 mm smaller (e.g., for a 7 mm Optio-C System lordotic spacer, the posterior height is 6 mm).



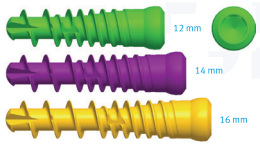
Optio-C Screws

All Optio-C System bone screws are 3.3 mm diameter, variable angle. Both self-drilling DiamondTip™ and self-tapping screw configurations are available in 12, 14, and 16 mm lengths. Screws feature dual-single lead, cortico-cancellous thread form and are color coded by length. Optio-C screws provide a lag effect designed to allow the interbody device to fit snugly to the anatomy.

Self-drilling screws can reduce the surgical steps required to penetrate the cortex of the vertebral body, and they are distinguished by black stripes on the top of the screw head.



ø3.3 mm Self-Drilling Variable Angle Screws
07.01875.012–016



ø3.3 mm Self-Tapping Variable Angle Screws
07.01874.012–016

Optio-C Plate/Screw Angulation

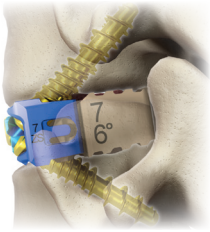
Optio-C System plates and screws allow for variable angle placement as follows:

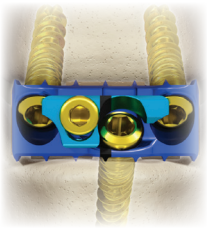
- The appropriate angle ranges for the lateral screws are 35° to 45° cephalad/caudal and –5° to 5° medial/lateral.
- The appropriate angle ranges for the midline screw are 35° to 45° cephalad/caudal and 0° to 10° medial/lateral.

The midline screw is offset by 1mm from the plate midline, and angles 5° medial toward midline.

The Optio-C PEEK implant can be implanted in two orientations:

- Standard orientation, two screws cephalad and one screw caudal
- Inverted orientation, one screw cephalad and two screws caudal



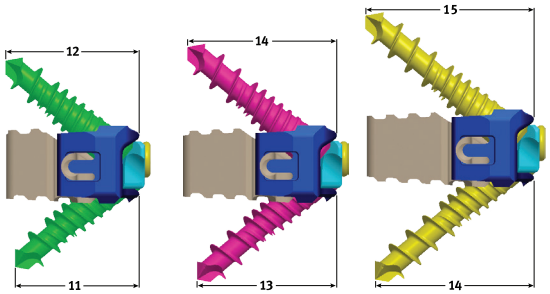


Standard

Inverted

Optio-C System Screw Length

Optio-C System screw lengths will terminate at the approximate anterior-posterior distances shown when inserted at nominal trajectory.



Optio-C PEEK Footprint	12 × 14 mm	14 × 16 mm	15 × 18 mm
Screw Length	12 mm	14 mm	16 mm

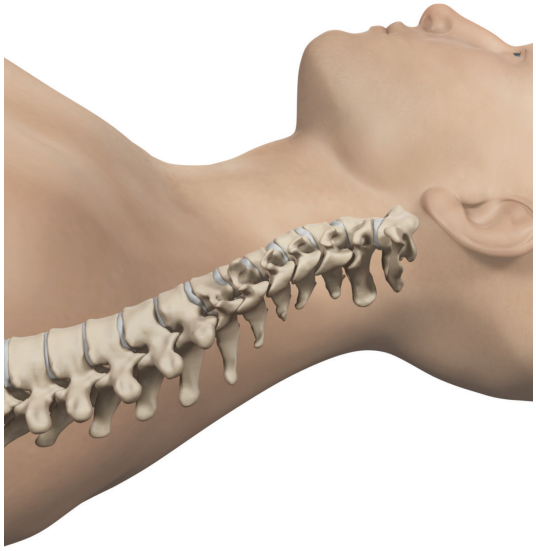


Figure 1

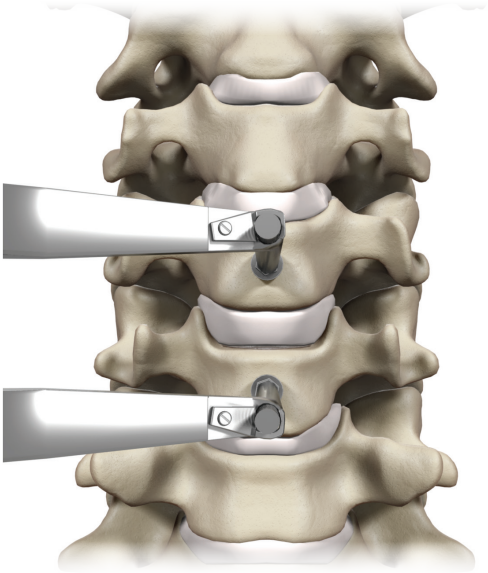


Figure 2

Pre-operative Planning and Patient Positioning

- Pre-operatively, the surgeon must identify the proper intervertebral level to fuse using diagnostic techniques such as radiographs, MRI, myelography, discography, patient history, and physical examination. Place the patient in supine position. Support the posterior cervical spine to maintain normal lordosis and choose a right- or left-sided approach. Identify the symptomatic level, and make a skin incision to the corresponding pathology (Figure 1).

Exposure, Location, and Site Preparation

- The anterior cervical anatomy is exposed in the standard fashion by identifying a dissection plane between the trachea and esophagus. Exposure is then held in place with self-retaining retractors (Figure 2).

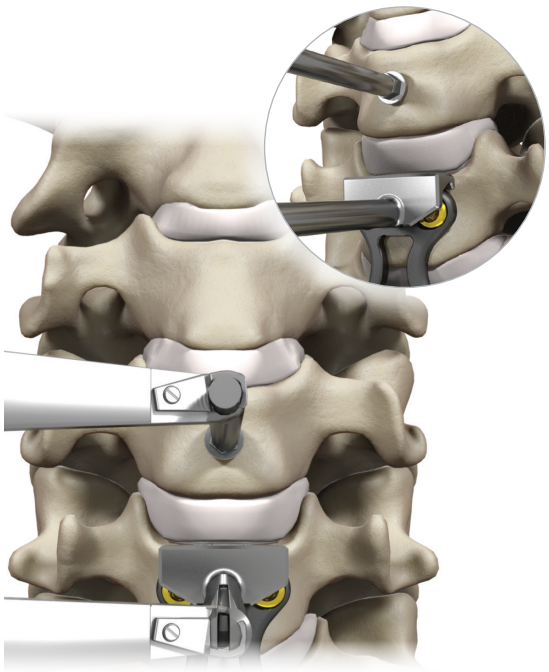


Figure 3

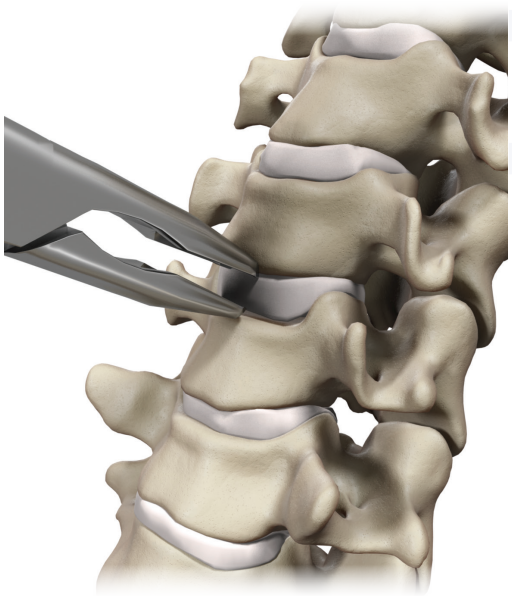


Figure 4

- For placement adjacent to existing plate hardware, the Optio-C distraction pin Instruments may be used with a Caspar distractor over the existing plate hardware in lieu of a Caspar pin in that vertebral segment (Figure 3).

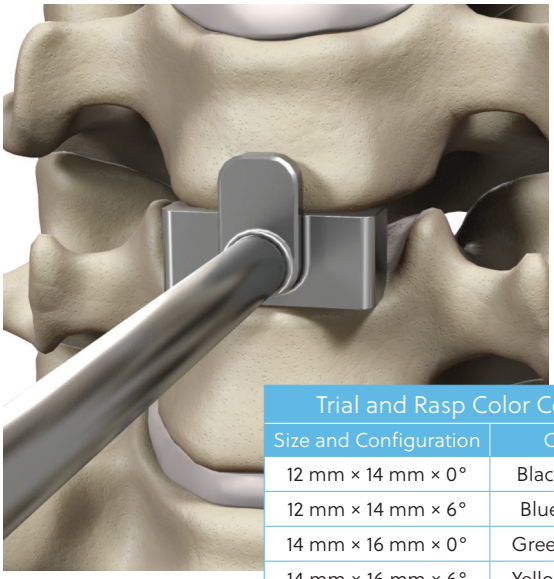
  Note: *Ensure that contacting surfaces between the distraction pin and existing hardware are clear of bone or soft tissue.*

  Note: *Optio-C distraction pins are intended for single use only and should be disposed of after one use.*

  Warning: *If existing hardware is present, compatibility between the distraction pin and the existing hardware should be verified before use. When the distraction pin is used with existing hardware, extreme care should be taken to prevent damage to existing hardware.*

- Prepare the anatomy to accommodate placement of the Optio-C implant. It is recommended to insert the Optio-C implant under distraction (Figure 4).

  Warning: *When preparing the disc space, care should be taken to ensure that an appropriate amount of bone is removed; excessive removal of bone has the potential to cause subsidence, while failing to remove enough bone has the potential to cause poor fusion.*



Trial and Rasp Color Code	
Size and Configuration	Color
12 mm × 14 mm × 0°	Black
12 mm × 14 mm × 6°	Blue
14 mm × 16 mm × 0°	Green
14 mm × 16 mm × 6°	Yellow
15 mm × 18 mm × 0°	Tan
15 mm × 18 mm × 6°	Orange

Figure 5

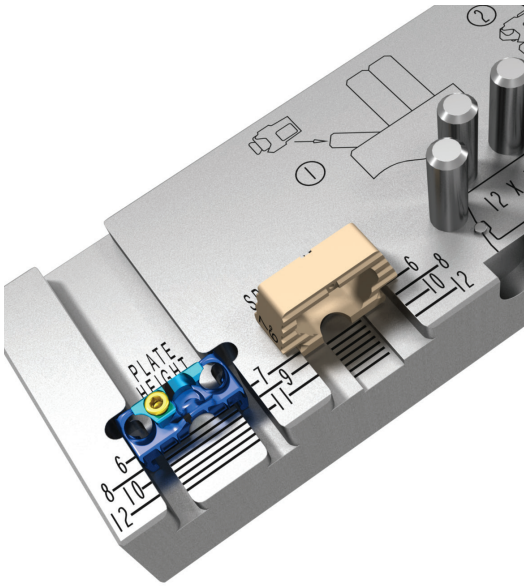


Figure 6

Implant Sizing

- Choose a parallel or lordotic trial to match the height and contour of the intervertebral space. Select the appropriate trial to assess the height of the disc space.
- Connect the modular impaction cap handle to the trial. Ensure that the Trial fits snugly in the disc space when distraction is released.
- Once the height is determined, select the appropriate implant footprint by using the trials and rasps (12 × 14, 14 × 16, or 15 × 18). These instruments equal the shape of the assembled implant (plate + PEEK spacer) (Figure 5).

  Note: *Intra-operative imaging can be used to confirm implant sizing. Optio-C System trials and rasps are designed to be line-to-line with the implant.*

Implant Assembly

- The Optio-C implant must be assembled before use (Figure 6). Confirm the chosen implant sizes and then remove the Optio-C plate and Optio-C spacer from their sterile packaging.

  Note: *Optio-C plate height and spacer height must match. For example, if the 7 mm trial fits appropriately, then a 7 mm plate and 7 mm spacer are used.*

  Note: *The sizing scale on the Implant assembly fixture can be used to confirm implant sizes before assembly.*

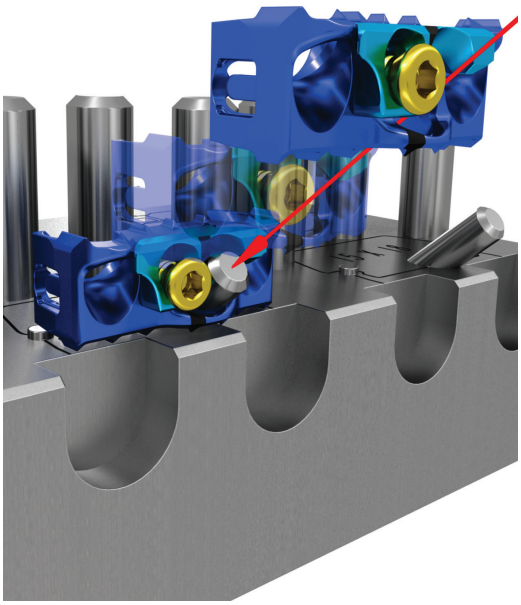


Figure 7

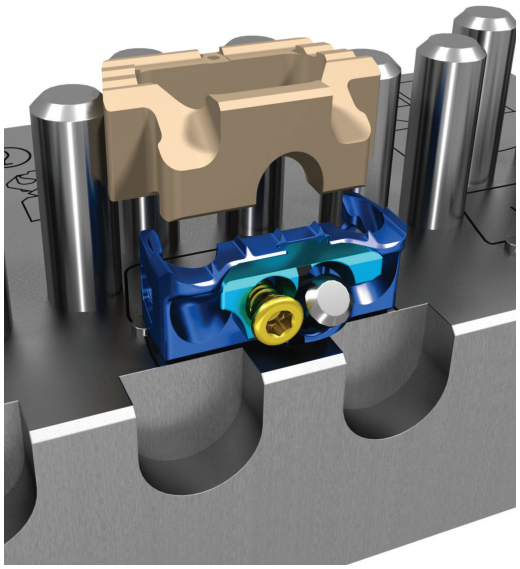


Figure 8

- Select the implant assembly block station to match the chosen implant footprint. Slide the plate over the short, angled pin. Guide the pin into the plate midline hole until the plate sits flat in the appropriate footprint station (Figure 7).

  Note: *The gold locking cap needs to be located on the left side of the angled pin.*

- Before connecting the spacer to the plate, ensure that the spacer notches for the lateral screws are facing upward. Place the spacer into the implant assembly block behind the plate between the four alignment pins (Figure 8).

Inserter Guide

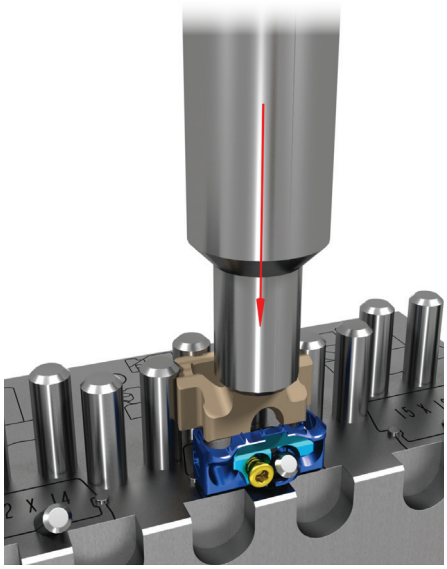


Figure 9

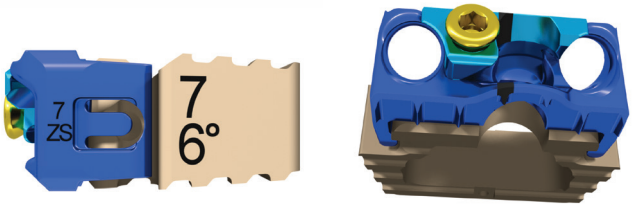


Figure 10

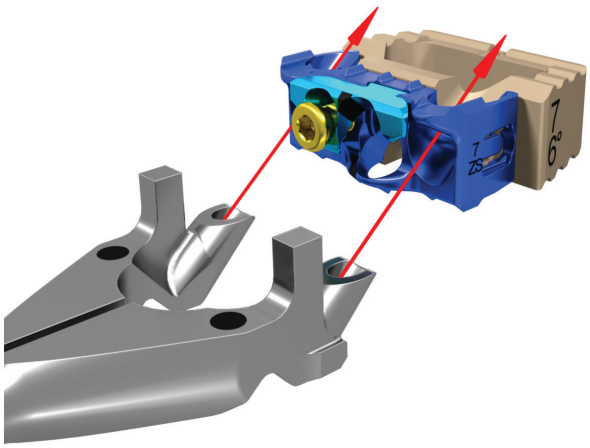


Figure 11

Implant Assembly *(continued)*

- Use the implant assembly tamp to connect the spacer to the plate until an audible click is heard (Figure 9).
- Confirm visually that the implant is assembled appropriately. Ensure that the plate and spacer sizes match and that the plate screw holes and spacer notches are aligned (Figure 10).

  Note: *The Optio-C implant can be loaded onto either Optio-C inserter guide directly from the implant assembly block.*

Attaching Implant

- Assemble the inserter guide to the modular impaction cap handle. Ensure that the inserter sleeve is in the unlocked position by pulling it toward the modular handle and rotating the sleeve counter-clockwise to engage the threads. With the gold locking screw oriented on the left and guide circular markings facing upward, insert the inserter guide tubes into the plate screw holes until the positive stops are in contact with the plate (Figure 11).

  Note: *The circular markings on the inserter guide should face upward when assembling the plate to the inserter. These markings are for orientation only, indicating the direction of the two lateral screws (two dots cephalad, two screws point cephalad).*

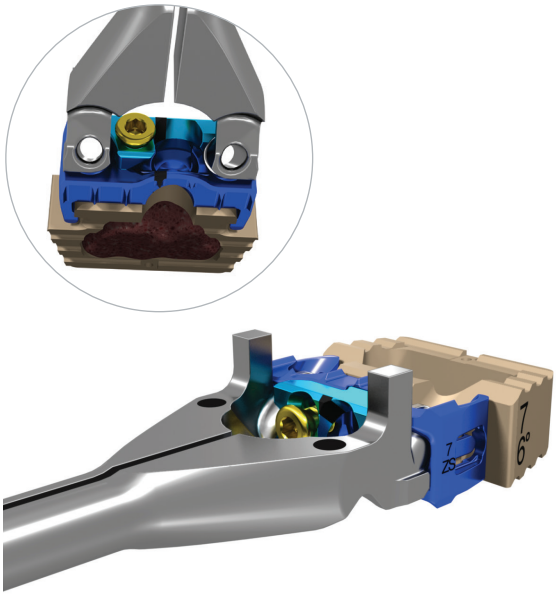


Figure 12

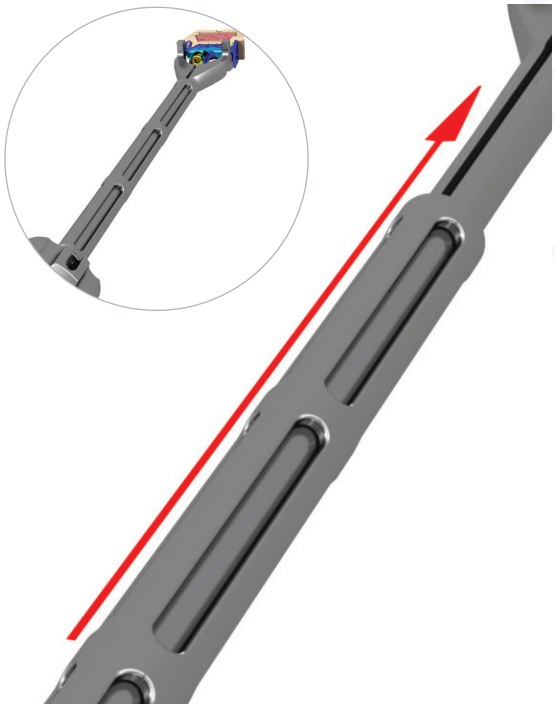


Figure 13

- Ensure that the inserter is fully seated in the plate holes and that the inserter guide positive stop is in contact with the plate. Verify the guide holes and lateral plate holes are aligned and that the inserter axis is perpendicular to the anterior face of the plate (Figure 12).
- Secure the implant by rotating the sleeve clockwise and sliding the inserter guide sleeve toward the plate until it bottoms out on the distal threads. Rotate the sleeve clockwise, engaging the threads until secure (Figure 13).

Inserter Guide *(continued)*

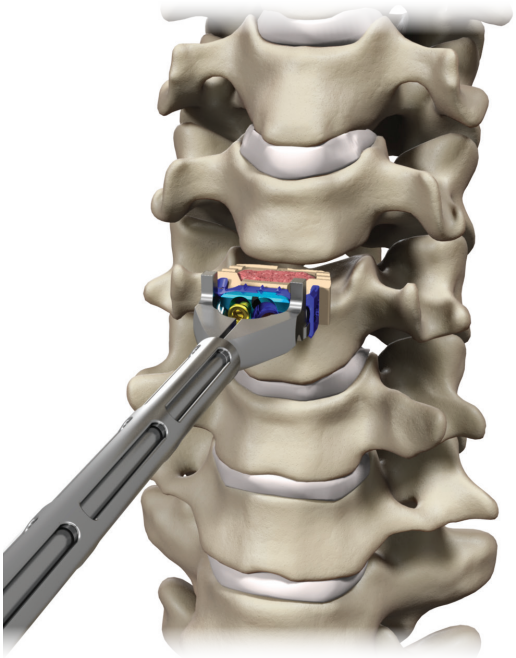


Figure 14

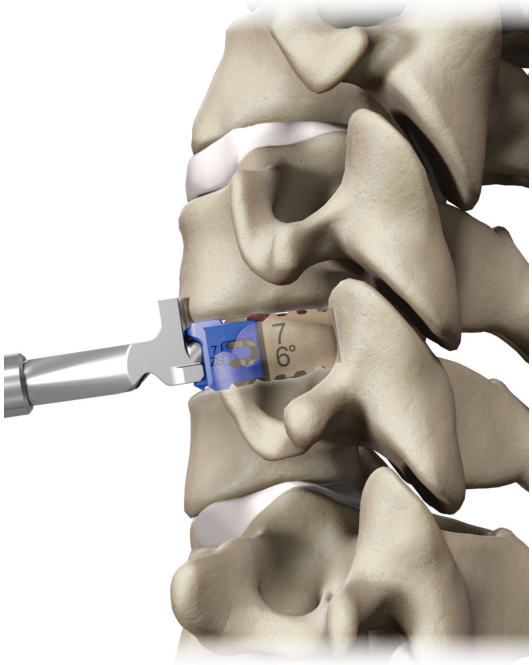


Figure 15

Implant Placement

- Once the implant is securely attached to the inserter, insert the implant into the distracted segment. If necessary, use light impaction to advance the plate into the disc space (Figure 14).

  Note: *Positive stops position the implant flush with the anterior aspect of the vertebral bodies.*

  Warning: *When inserting the implant, ensure a tight fit between the inserter and implant. Release distraction before drilling to prevent shifting.*

  Warning: *When inserting the implant, care should be taken to avoid using excessive force, which has the potential to cause damage to the implant or surrounding tissue.*

- Ensure that the implant fits snugly between the adjacent vertebrae, and then release distraction while leaving the inserter guide attached to the plate. The modular handle can be temporarily removed from the inserter to increase visibility for screw preparation and delivery (Figure 15).

  Note: *If using the distraction pin, remove the distraction pin with the Caspar distractor.*

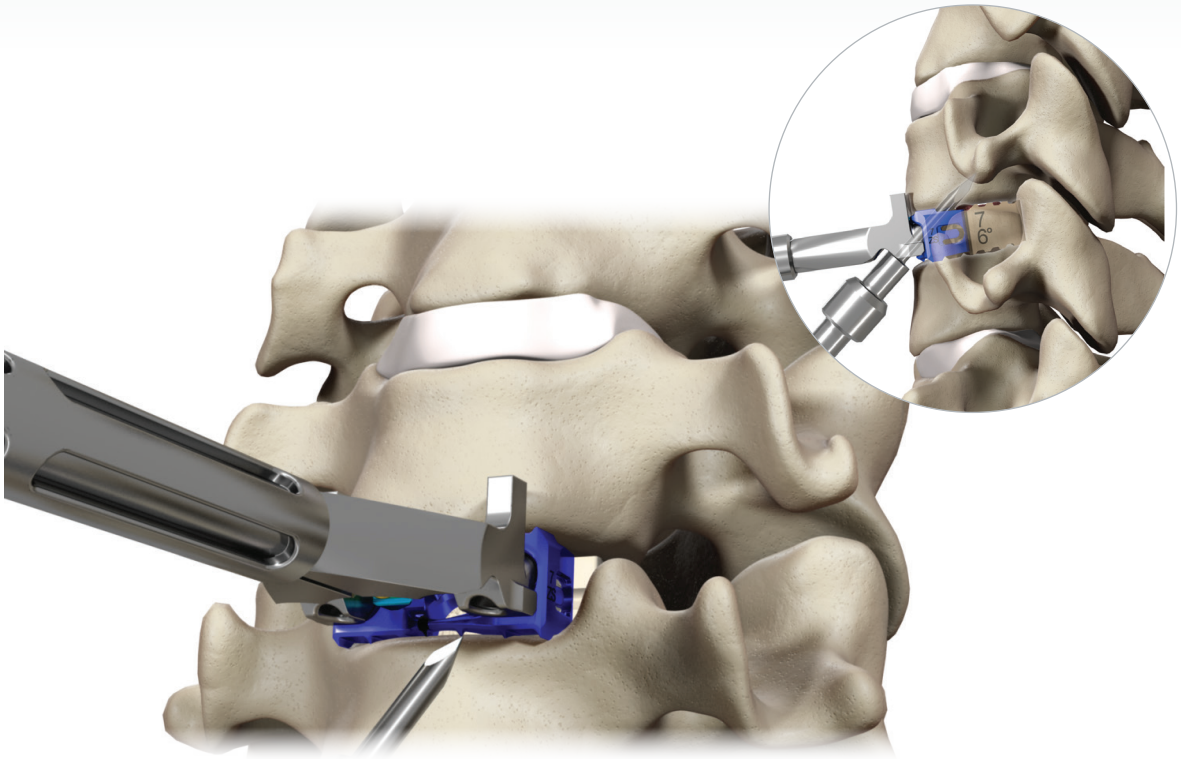


Figure 16

Lateral Screw Hole Preparation/Screw Placement

- Assemble the awl/drill to the modular spin cap handle. Create a pilot hole for the first lateral screw hole by placing the awl/drill through the guide hole of the inserter guide until the positive stop on the awl/drill contacts the guide. The awl/drill will create a pilot hole 6 mm deep on the screw hole axis (40°).
- The inserter guide allows the awl/drill (straight, flexible, or U-joint options) to pass through the guide holes to prepare the two lateral screw holes while the inserter guide is secured to the implant.
- Intra-operative imaging should be used to verify awl/drill position and to determine the appropriate length screw. Remove the awl/drill. Repeat the same steps on the contralateral side. Remove the inserter guide by rotating the sleeve counter-clockwise and then pulling the inserter sleeve toward the modular impaction cap handle and pulling the inserter away from the implant (Figure 16).

Note: *Lateral screw preparation and placement should precede midline screw preparation and placement.*

Note: *An optional tissue sleeve assembly can be used over the U-joint instrumentation if desired. The tissue sleeve assembly helps shield the U-joint from tissue and fixes the instrument tip at a 40° angle. Prior to attaching the modular spin cap handle to the U-joint instrument, the U-joint sleeve tip is threaded clockwise onto the U-joint sleeve tube to encase the universal joint.*

Inserter Guide *(continued)*

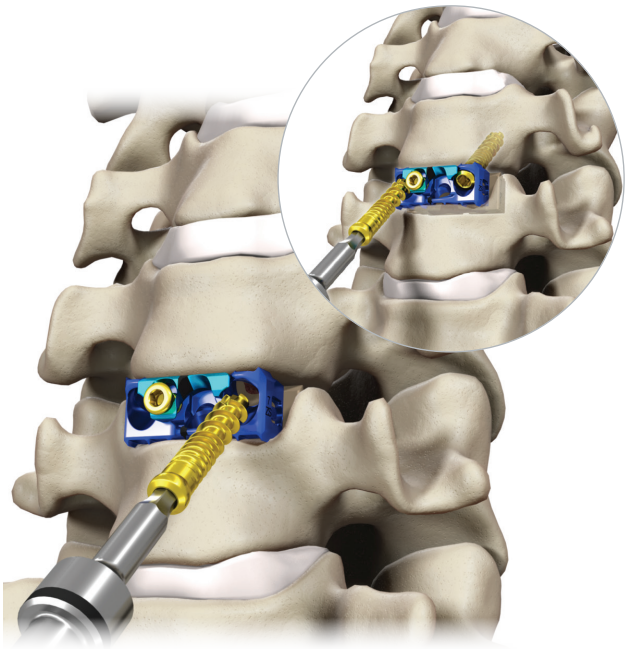


Figure 17

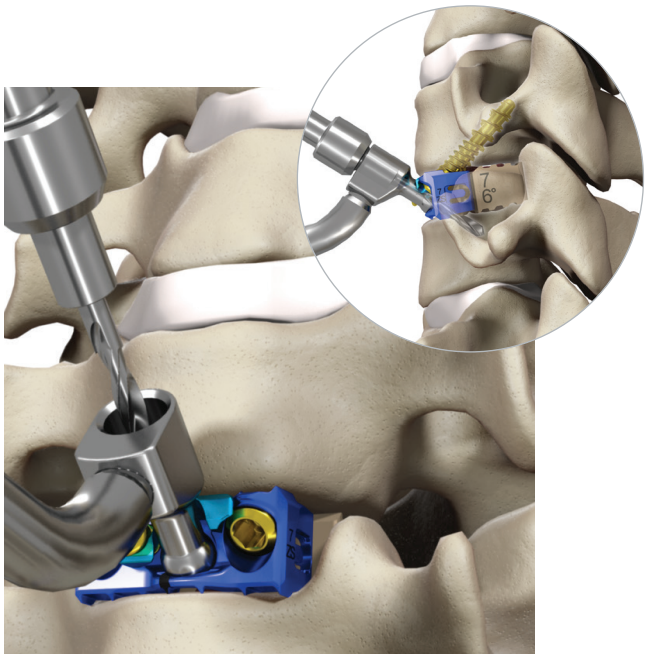


Figure 18

Lateral Screw Hole Preparation/ Screw Placement *(continued)*

- Assemble the 2.0 mm hex driver and modular spin cap handle. Load the desired screw onto the driver and insert the screw through the first lateral screw hole, advancing the screw until the screw head contacts the plate to stabilize the implant provisionally. Ensure the driver is on axis to the prepared screw trajectory during screw insertion. Repeat on the contralateral side (Figure 17).

  Warning: *During screw insertion, care should be taken to avoid bone screw stripping, which has the potential to cause an unstable screw construct.*

Midline Screw Hole Preparation/ Screw Placement

- Prepare the midline screw hole using the fixed angle guide or variable angle guide. The appropriate angle ranges for the midline screw are 35° to 45° cephalad/ caudal and 0° to 10° medial/lateral.

  Note: *The variable angle guide allows for screw trajectories within the acceptable limits. The fixed angle guide is designed for repeatable nominal angle placement.*

- The fixed angle guide or variable angle guide allows the awl/drill (straight, flexible, or U-joint options) to prepare for the midline screw hole. Seat the guide tip into the medial screw hole. Place the awl/drill through the selected drill guide until the positive stop contacts the guide. The awl/ drill will create a pilot hole 6 mm deep. Intra-operative imaging should be used to verify awl/drill position and determine the appropriate length screw (Figure 18).

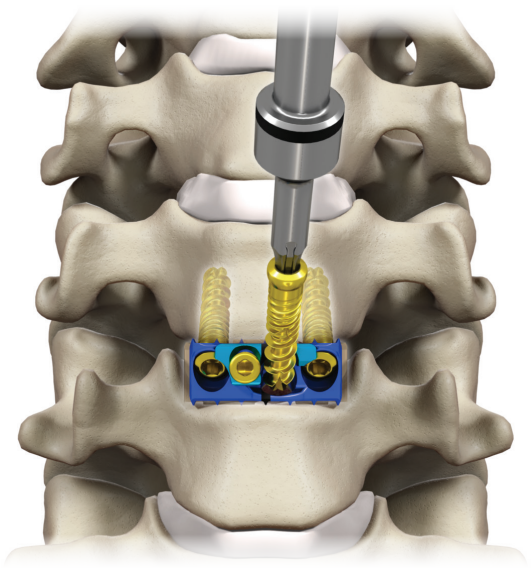


Figure 19

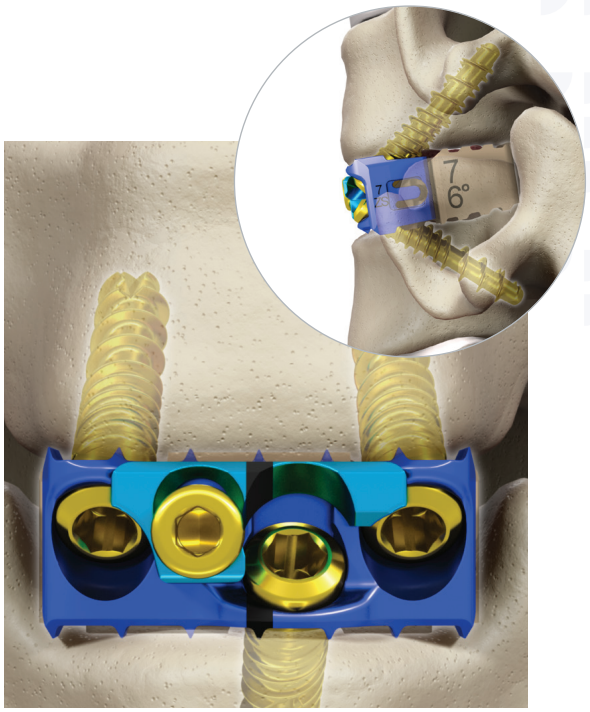


Figure 20

- Remove the awl/drill and guide. Load the desired screw onto the 2.0 mm hex driver. Insert the screw through the midline screw hole, advancing the screw until the screw head contacts the plate to stabilize the implant. Ensure that the driver is on axis to the prepared screw trajectory during screw insertion and final tightening (Figure 19).

Final Tightening of Bone Screws

- Completely engage the 2.0 mm hex driver in each screw head and fully seat all bone screws (Figure 20).

  Note: *Failure to fully seat the screws could interfere with the final tightening of the locking mechanism.*

  Note: *The locking mechanism comes in the unlocked position. Do not turn the gold locking screw counter-clockwise for any reason other than revision surgery.*

  Note: *Confirm that the screws are fully seated before securing the gold locking screw. If the teal locking cap does not move freely over the screw heads, re-check whether the bone screws are fully seated.*

Inserter Guide *(continued)*

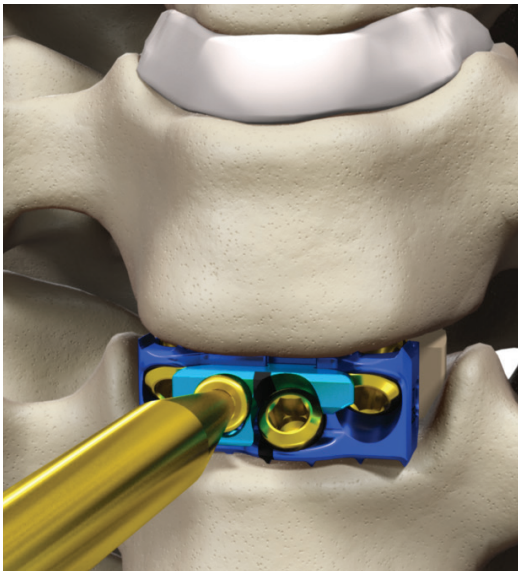


Figure 21

Figure 22

Securing the Locking Cap

- Once all screws are fully seated within the plate, assemble the gold locking cap driver and torque limiting handle. Insert the locking cap driver into the gold locking screw. Ensure that the tip of the driver is fully seated in the screw pocket and that the driver is on axis to the locking screw (Figure 21).
- Turn the driver clockwise. As the screw tightens, the teal locking cap will slide over the screw heads. Turn the torque limiting handle until an audible click is heard when the locking mechanism is tightened to 4 in-lb. The locking mechanism and torque limiting handle will provide visual, audible, and tactile confirmation that the locking mechanism is fully secured and the screw heads are partially covered (Figure 22).

Optional ATO Inserter Guide

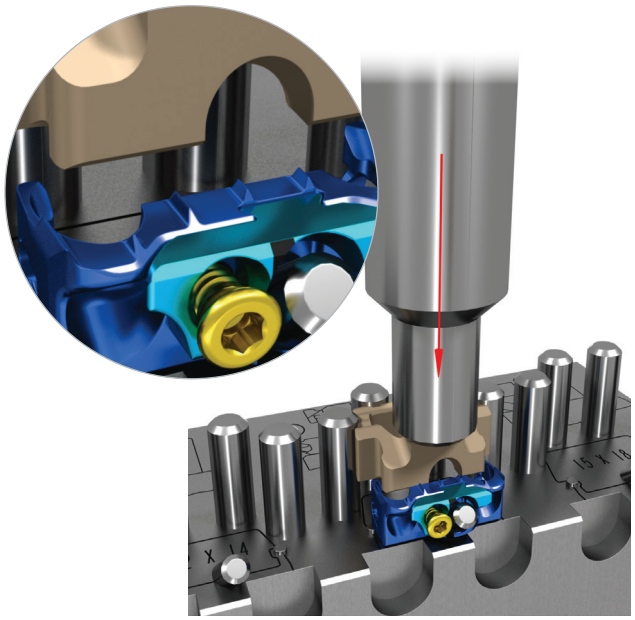


Figure 23

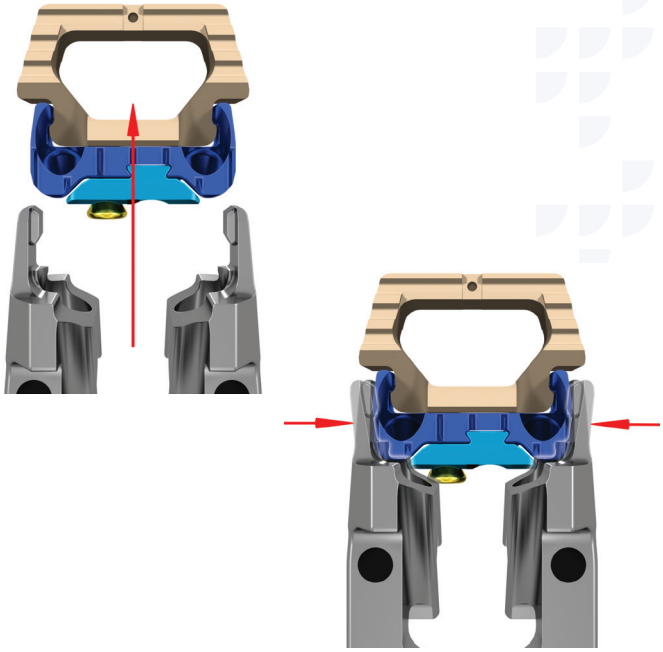


Figure 24

Planning, Positioning, and Exposure

- Repeat the steps for Pre-Operative Planning and Patient Positioning through Implant Assembly on pages 6–10 (Figure 23).

Attaching the Implant to the ATO Inserter Guide

- Assemble the ATO inserter guide to the modular impaction cap handle. The ATO inserter guide grasps the outside of the plate by engaging the plate pockets. With the gold locking screw oriented on the left and guide circular markings facing upward, attach the ATO inserter guide around the outside of the plate. The ATO inserter guide snaps into place when the tabs are fully seated in the plate pockets (Figure 24, top).

  Note: *The circular markings on the ATO inserter guide should face upward when assembling the plate to the inserter. These markings are for orientation only, indicating the direction the two lateral screws will point in situ (Figure 24, bottom).*

Optional ATO Inserter Guide *(continued)*

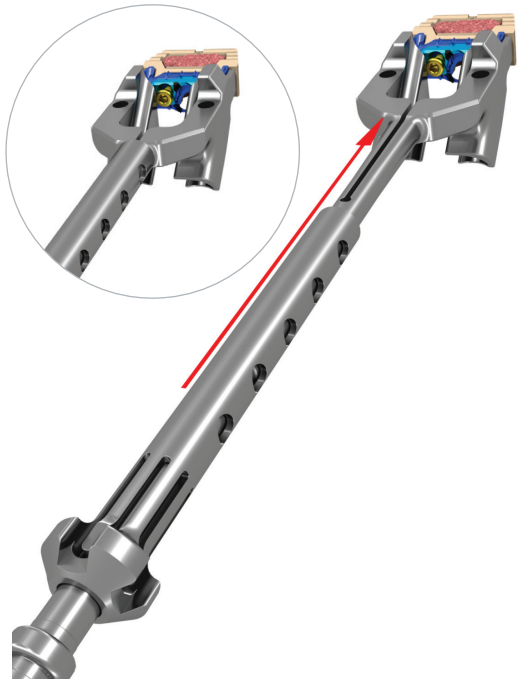


Figure 25

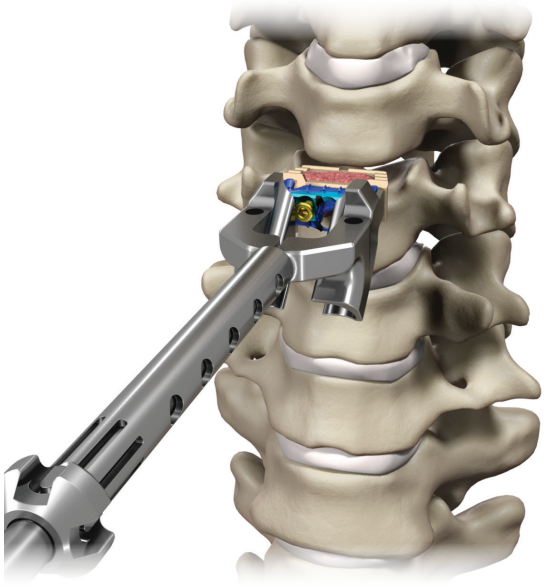


Figure 26

Attaching the Implant to the ATO Inserter Guide *(continued)*

- Ensure that the inserter is fully seated on the implant by verifying that the ATO inserter guide positive stops are in contact with the plate. Verify that the guide holes and lateral plate holes are aligned, and that the inserter axis is perpendicular to the anterior face of the plate (Figure 25).
- Secure the implant by sliding the ATO inserter guide sleeve toward the implant until it bottoms out on the distal end of the ATO inserter guide (Figure 25, inset).

  Note: *When using the ATO inserter guide, care should be taken to insert the implant in line to the disc space. Avoid off-axis loading or torsion of the ATO inserter guide during insertion of the implant to reduce risk of separating the plate from the PEEK spacer.*

Implant Placement

- Insert the implant into the distracted segment. If necessary, use light impaction to advance the implant into the disc space (Figure 26).

  Note: *Positive stops position the implant flush with the anterior aspect of the vertebral bodies.*

  Warning: *When inserting the implant, care should be taken to avoid using excessive force, which has the potential to cause damage to the implant or surrounding tissue.*

  Warning: *When inserting the implant, ensure a tight fit between the inserter and implant. Release distraction before drilling to prevent shifting.*

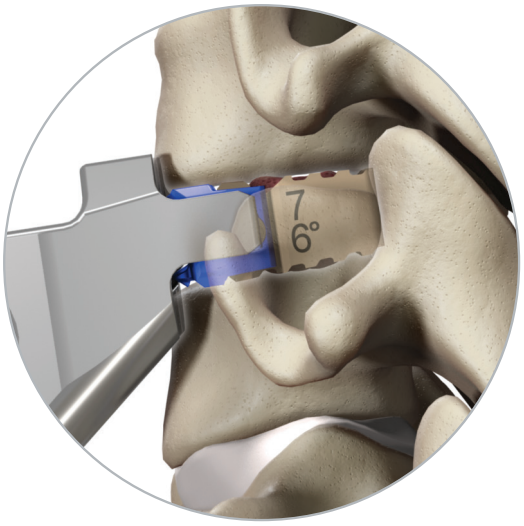


Figure 27

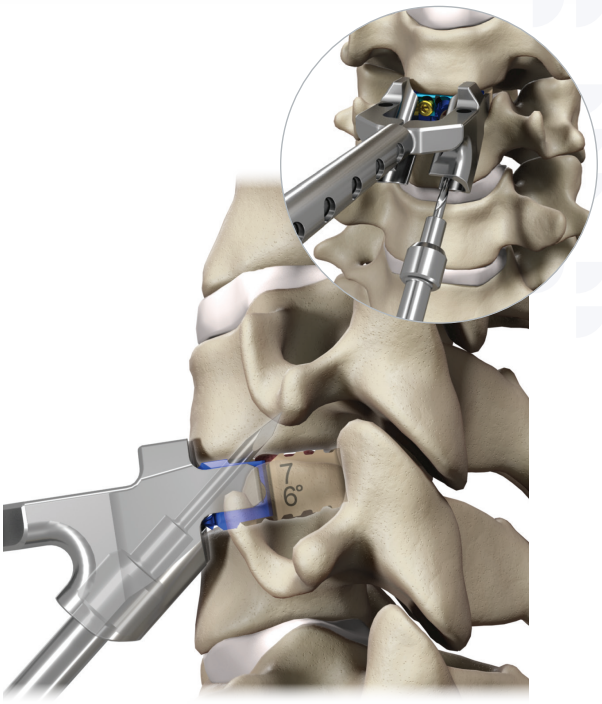


Figure 28

- Ensure that the implant fits snugly between the adjacent vertebrae, and then release distraction while leaving the ATO inserter guide attached to the implant construct. The modular handle can be temporarily removed from the inserter to increase visibility for screw preparation and delivery (Figure 27).

  Note: *If using the distraction pin, remove the distraction pin with the Caspar distractor.*

Lateral Screw Hole Preparation/ Screw Placement

- The ATO inserter guide allows the awl, drill, and 2.0 mm hex driver (straight and flexible options only) to pass through the guide holes for the two lateral screw holes while the ATO inserter guide is secured to the implant. The U-joint instruments are not compatible with the ATO inserter guide.
- Assemble the awl/drill to the modular spin cap handle. Create a pilot hole for the first lateral screw hole by placing the awl/drill through the guide hole of the ATO inserter guide until the positive stop contacts the ATO inserter guide. The awl/drill will create a pilot hole 6 mm deep on the screw hole axis (40°). Intra-operative imaging should be used to verify awl/drill position and to determine the appropriate length screw. Remove the awl/drill. Repeat the same steps on the contralateral side (Figure 28).

Optional ATO Inserter Guide *(continued)*

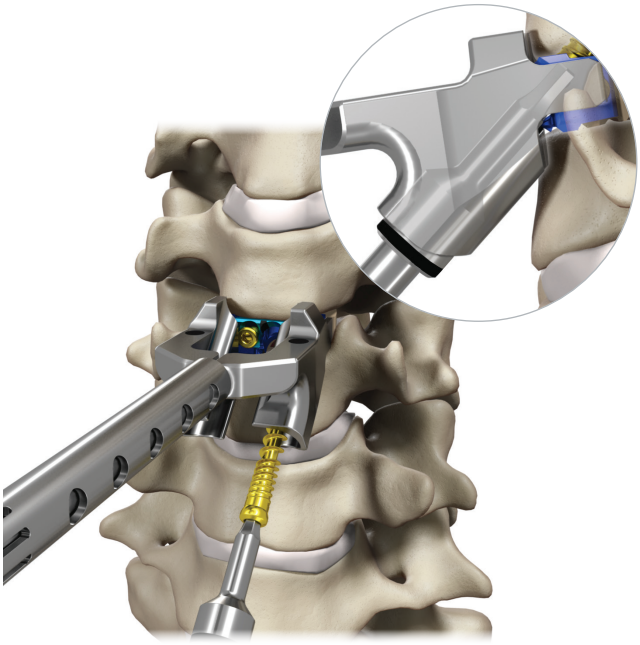


Figure 29

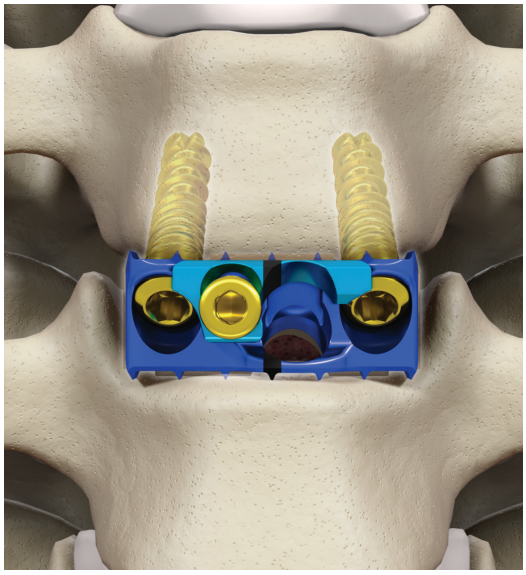


Figure 30

Lateral Screw Hole Preparation/Screw Placement *(continued)*

- Assemble the 2.0 mm hex driver and modular spin cap handle. Load the desired screw onto the driver and insert the screw through the first lateral screw hole until the screw head contacts the plate to stabilize the implant provisionally. Ensure that the driver is on axis to the prepared screw trajectory during screw insertion and final tightening (Figure 29).
- The driver laser marking approaches the edge of the guide tube to indicate the screw is nearly seated (Figure 29, inset).
- Repeat the previous step on the contralateral side. When both lateral screws have been placed, remove the ATO inserter guide by sliding the inserter sleeve toward the modular impaction cap handle and pulling the inserter away from the implant using a gentle, side-to-side motion (Figure 30).

Note: *If self-drilling screws are used, the awl/drill steps can be omitted at the discretion of the surgeon.*

Warning: *During screw insertion, care should be taken to avoid bone screw stripping, which has the potential to cause an unstable screw construct.*

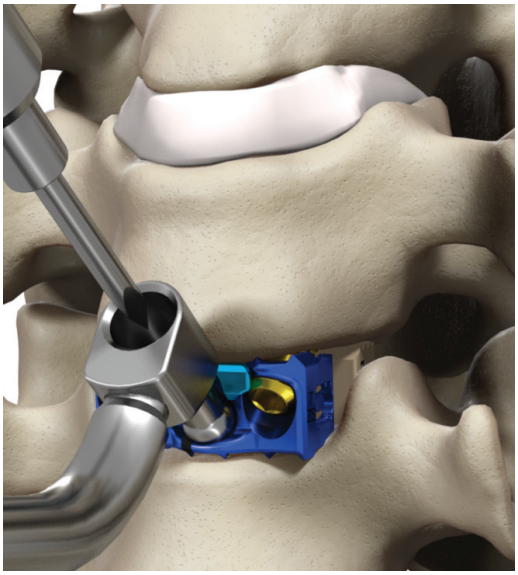


Figure 31

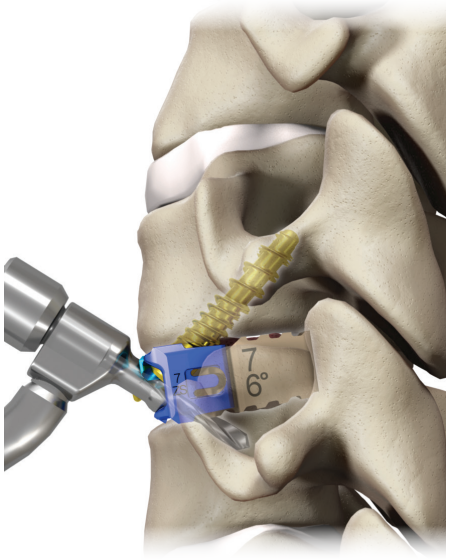


Figure 32

Midline Screw Hole Preparation/ Screw Placement

- Prepare the midline screw hole using the fixed or variable drill guide. The appropriate angle ranges for the midline screws are 35° to 45° cephalad/caudal and 0° to 10° medial/lateral (Figure 31).

  Note: *The variable angle guide allows for screw trajectories within the acceptable limits. The fixed angle guide is designed for repeatable nominal angle placement.*

- The fixed or variable drill allows the awl/drill (straight, flexible, or U-joint options) to prepare for the midline screw hole. Seat the guide tip into the medial screw hole. Place the awl/drill through the selected drill guide until the positive stop contacts the guide. The awl/drill will create a pilot hole 6 mm deep.
- Intra-operative imaging should be used to verify awl or drill position and determine the appropriate length screw (Figure 32).

  Note: *An optional tissue sleeve assembly may be used over the U-joint instrumentation if desired. The tissue sleeve assembly helps shield the U-joint from tissue and fixes the instrument tip at a 40° angle. Prior to attaching the modular spin cap handle to the U-joint instrument, the U-joint sleeve tip is threaded clockwise onto the U-joint sleeve tube to encase the universal joint.*

Optional ATO Inserter Guide *(continued)*

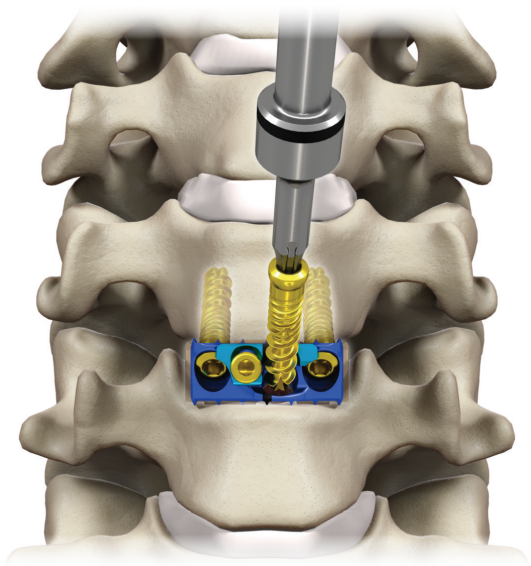


Figure 33

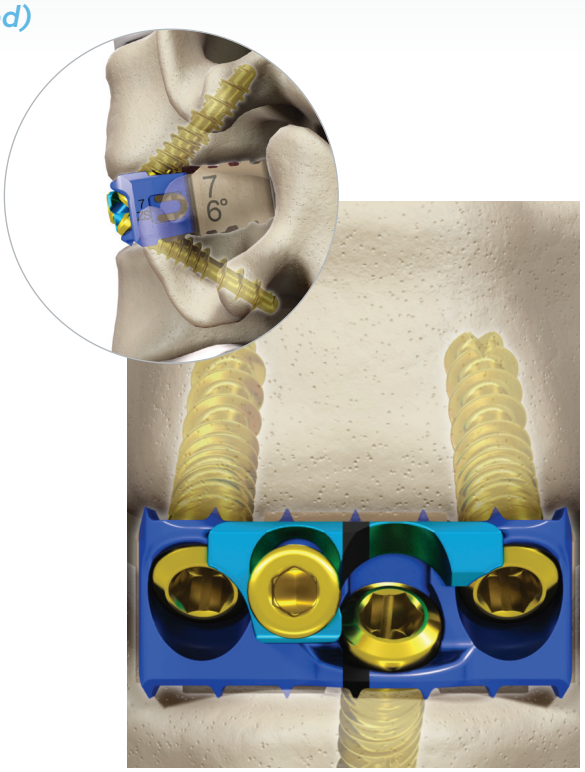


Figure 34

Midline Screw Hole Preparation/ Screw Placement *(continued)*

- Remove the awl/drill and guide. Load the desired screw onto the 2.0 mm hex driver. Insert the screw through the midline screw hole, advancing the screw until the screw head contacts the plate to provisionally stabilize the implant. Ensure that the driver is on axis to the prepared screw trajectory during screw insertion and final tightening (Figure 33).

  Warning: *During screw insertion, care should be taken to avoid bone screw stripping, which has the potential to cause an unstable screw construct.*

Final Tightening of Bone Screws

- Completely engage the driver in each screw head and fully seat all bone screws (Figure 34).

  Note: *Failure to fully seat the screws could interfere with the final tightening of the locking mechanism.*

  Note: *The locking mechanism comes in the unlocked position. Do not turn the gold locking screw counter-clockwise for any reason other than revision surgery.*

  Note: *Confirm that the screws are fully seated before securing the gold locking screw. If the teal locking cap does not move freely over the screw heads, re-check whether the bone screws are fully seated.*

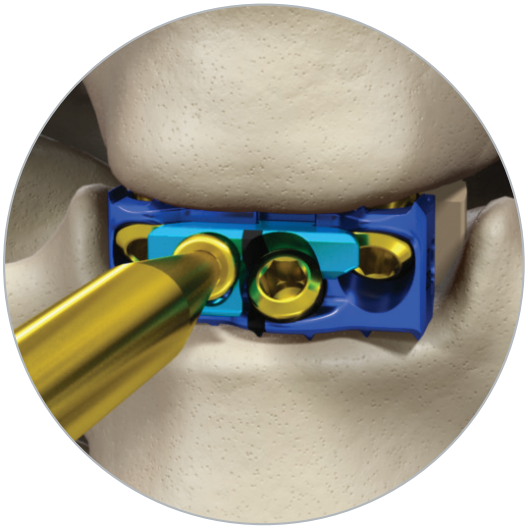


Figure 35

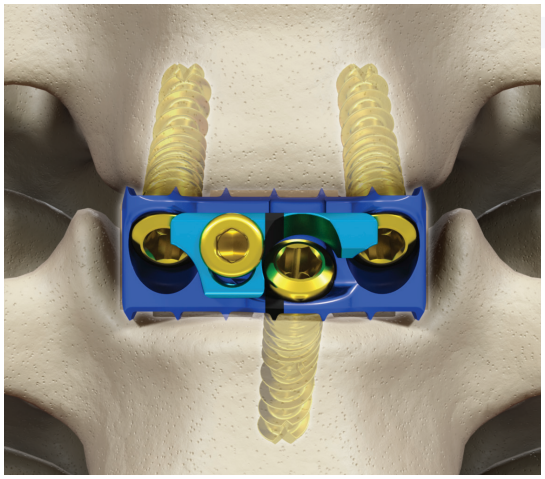


Figure 36

Securing the Locking Cap

- Once all screws are fully seated within the plate, assemble the gold locking cap driver and torque limiting handle. Insert the locking cap driver into the gold locking screw. Ensure that the tip of the driver is fully seated in the screw pocket and that the driver is on axis to the locking screw (Figure 35).
- Turn the driver clockwise. As the screw tightens, the teal locking cap will slide over the screw heads. Turn the torque limiting handle until an audible click is heard when the locking mechanism is tightened to 4 in-lb. The locking mechanism and torque limiting handle will provide visual, audible and tactile confirmation that the locking mechanism is fully secured and the screw heads are partially covered (Figure 36).

Freehand Screw Insertion

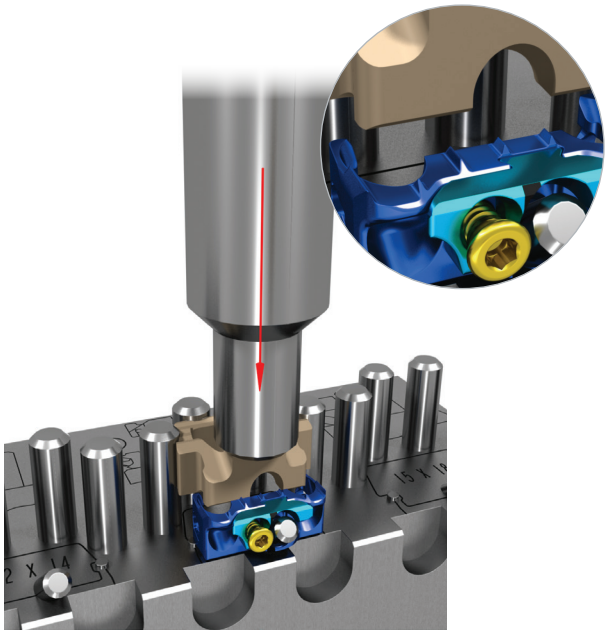


Figure 37

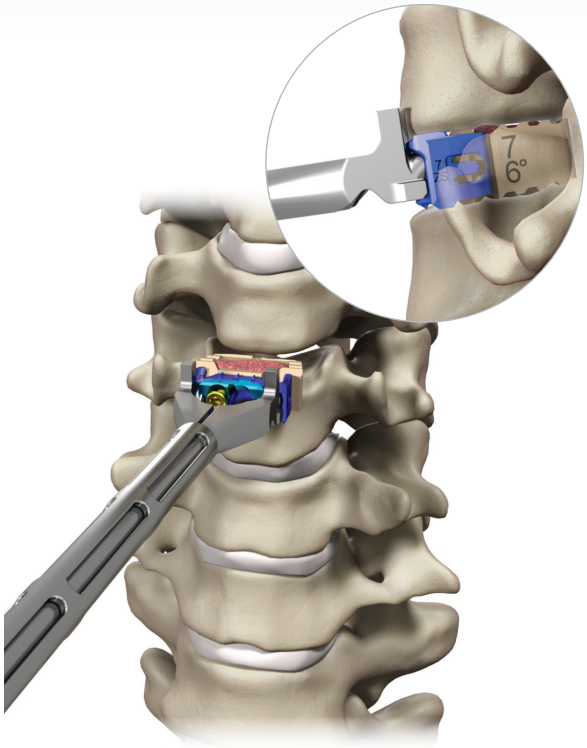


Figure 38

Planning, Positioning, and Exposure

- Repeat the steps for Pre-Operative Planning and Patient Positioning through Implant Assembly on pages 6–10 (Figure 37).

Implant Insertion

- Once the implant is attached securely to the inserter, insert the implant into the distracted segment. If necessary, use light impaction to advance the plate into the disc space (Figure 38).

  Note: *Positive stops position the implant flush with the anterior aspect of the vertebral bodies.*

  Warning: *When inserting the implant, ensure a tight fit between the inserter and implant. Release distraction before drilling to prevent shifting.*

  Warning: *When inserting the implant, care should be taken to avoid using excessive force, which has the potential to cause damage to the implant or surrounding tissue.*

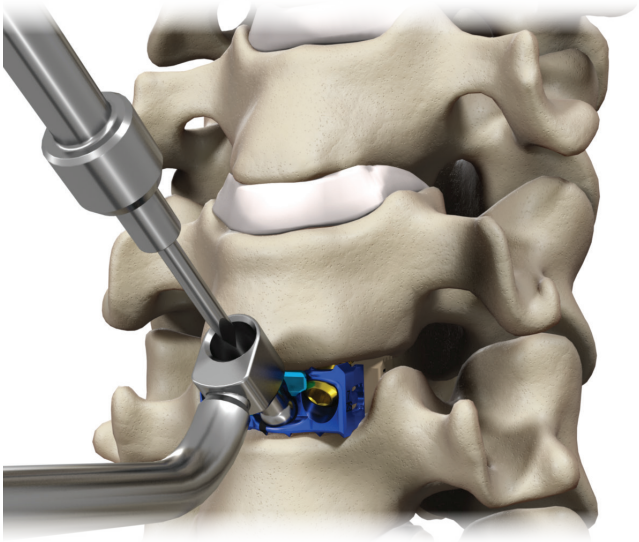


Figure 39

Screw Hole Preparation/Screw Placement

- Remove the Inserter from the implant. Assemble the awl/drill and the modular spin cap handle. Place the fixed angle guide or variable angle guide in the selected screw hole. Ensure that the guide tip is fully seated.
- The appropriate angle ranges for the midline screw are 35° to 45° cephalad/caudal and 0° to 10° medial/lateral.
- The appropriate angle ranges for the lateral screws are 35° to 45° cephalad/caudal and -5° to 5° medial/lateral.

  Note: *The variable angle guide allows for screw trajectories within the acceptable limits. The fixed angle guide is designed for repeatable nominal angle placement.*

- Prepare the midline screw hole using the fixed or variable drill guide. The fixed or variable drill allows the awl/drill (straight, flexible, or U-joint options) to prepare for the midline screw hole. Seat the guide tip into the medial screw hole. Place the awl/drill through the selected drill guide until the positive stop contacts the guide. The awl/drill will create a pilot hole 6 mm deep. Intra-operative imaging should be used to verify awl/drill position and determine the appropriate length screw (Figure 39).

  Note: *The Optio-C System includes an optional tamp that can be used with the modular impaction cap handle to provide minor adjustments to the plate in situ. Adjustments should be made only under slight distraction. Care should be taken when using the tamp because it does not have a positive stop.*

Freehand Screw Insertion *(continued)*

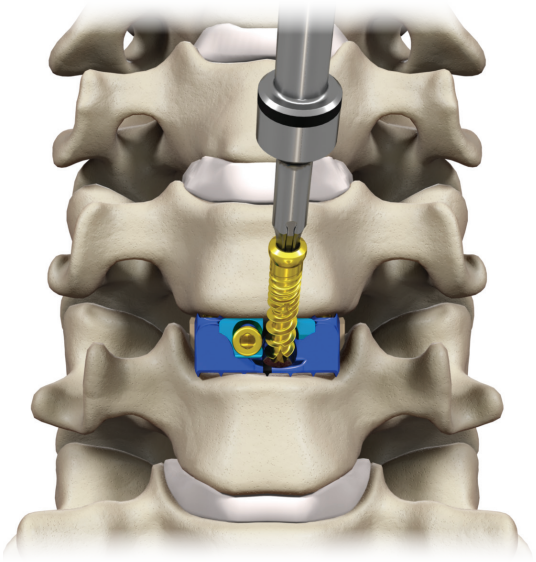


Figure 40

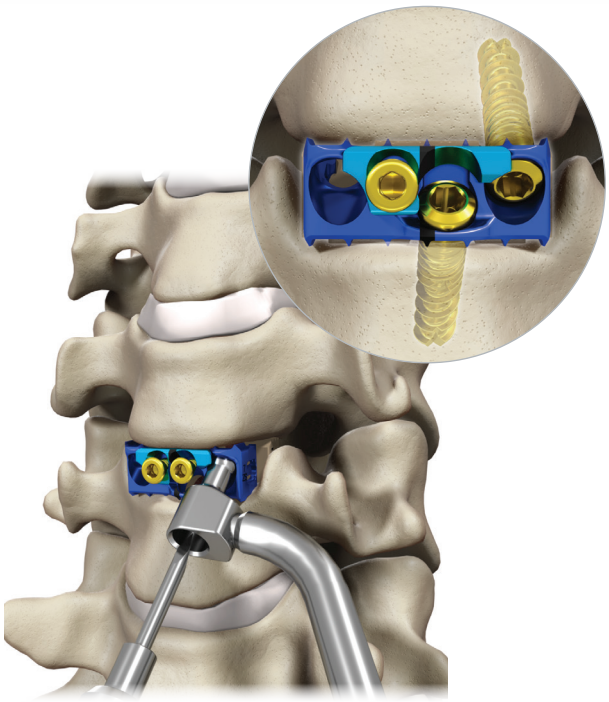


Figure 41

Screw Hole Preparation/Screw Placement *(continued)*

- Remove the awl/drill and guide. Load the desired screw onto the 2.0 mm hex driver. Insert the screw through the midline screw hole, advancing the screw until the screw head contacts the plate to provisionally stabilize the implant (Figure 40).

  Note: *An optional tissue sleeve assembly may be used over the U-joint instrumentation if desired. The tissue sleeve assembly helps shield the U-joint from tissue and fixes the instrument tip at a 40° angle. Prior to attaching the modular spin cap handle to the U-joint instrument, the U-joint sleeve tip is threaded clockwise onto the U-joint sleeve tube to encase the universal joint.*

- Repeat these steps for the lateral screws, using the same "drill-and-fill" technique (Figure 41).

  Note: *Use care to maintain the implant positioning while preparing the screw hole.*

  Warning: *During screw insertion, care should be taken to avoid bone screw stripping, which has the potential to cause an unstable screw construct.*

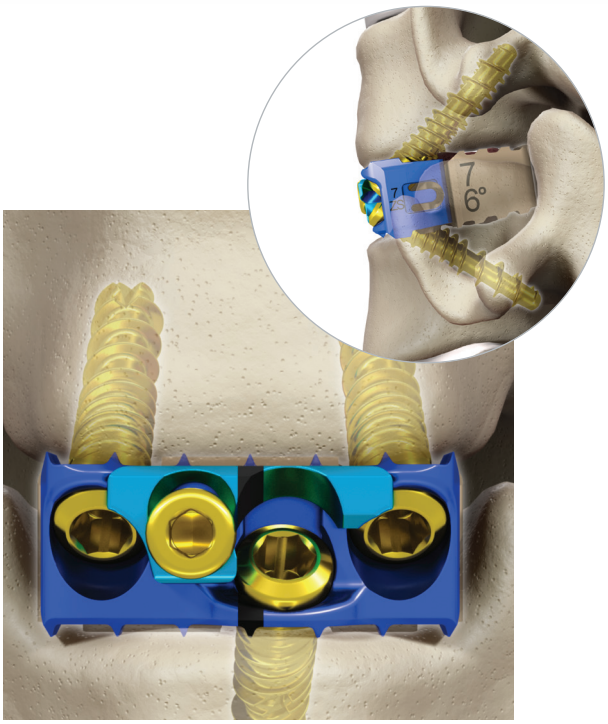


Figure 42

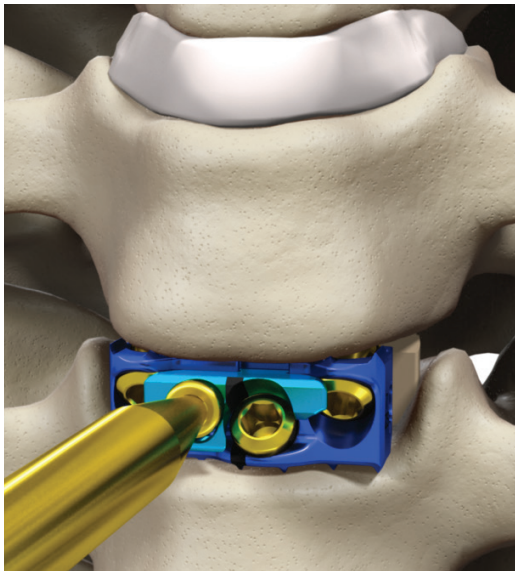


Figure 43

Final Tightening of Bone Screws

- Completely engage the 2.0 mm hex driver in each screw head, and fully seat all bone screws (Figure 42).

  Note: *Failure to fully seat the screws could interfere with the final tightening of the locking mechanism.*

  Note: *The locking mechanism comes in the unlocked position. Do not turn the gold locking screw counter-clockwise for any reason other than revision surgery.*

  Note: *Confirm that the screws are fully seated before securing the gold locking screw. If the teal locking cap does not move freely over the screw heads, re-check whether the bone screws are fully seated.*

Securing the Locking Cap

- Once all screws are fully seated within the plate, assemble the gold locking cap driver and torque limiting handle. Insert the locking cap driver into the gold locking screw. Ensure that the tip of the driver is fully seated in the screw pocket and that the driver is on axis to the locking screw (Figure 43).

Freehand Screw Insertion *(continued)*

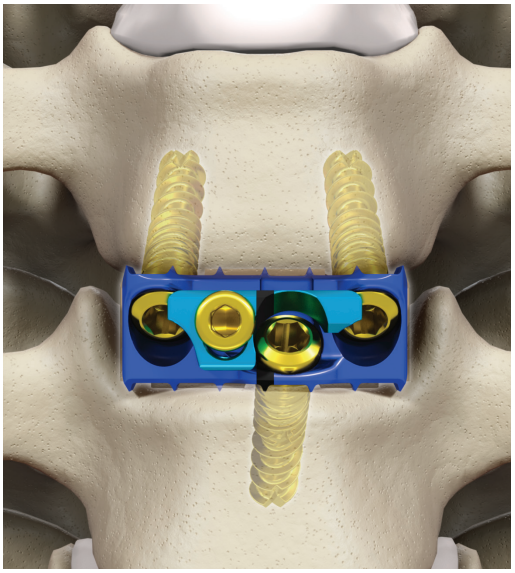


Figure 44

Securing the Locking Cap *(continued)*

- Turn the driver clockwise. As the screw tightens, the teal locking cap will slide over the screw heads. Turn the torque limiting handle until an audible click is heard when the locking mechanism is tightened to 4 in-lb. The locking mechanism and torque limiting handle will provide visual, audible, and tactile confirmation that the locking mechanism is fully secured and the screw heads are partially covered (Figure 44).

Removal/Revision

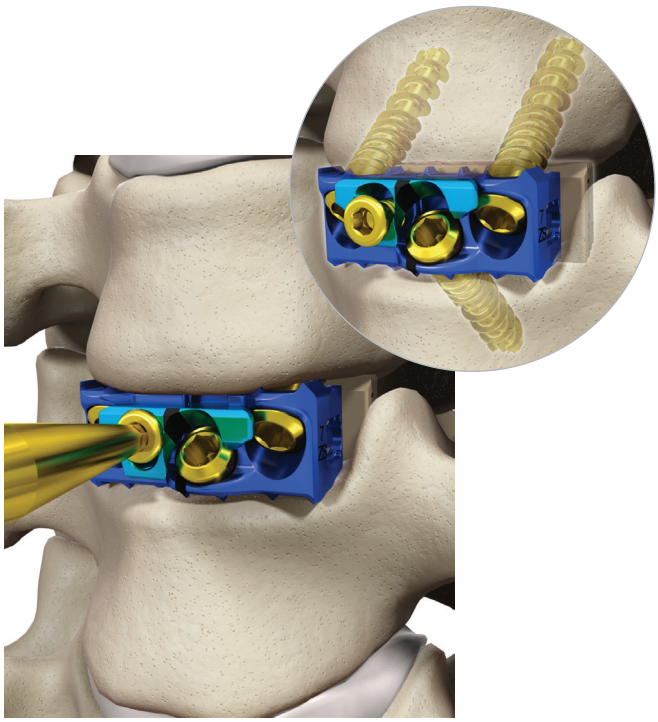


Figure 45

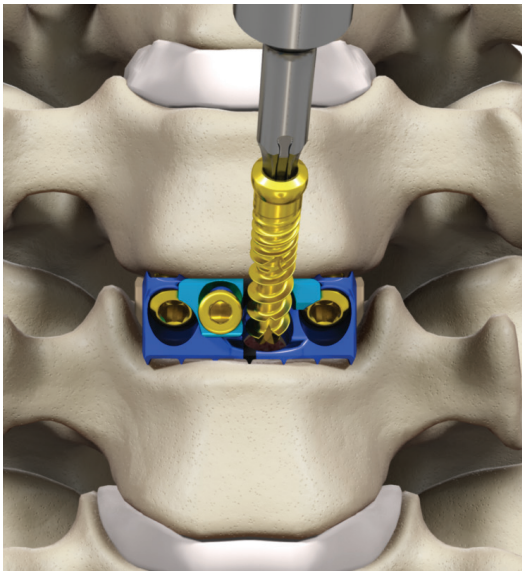


Figure 46

Implant Revision/Removal

- The gold locking cap driver, torque limiting handle, 2.0 mm hex driver, modular spin cap handle, inserter guide, and modular impaction cap handle are needed for revision/removal cases.

  Note: *Appropriate distraction is required to remove the implant from the disc space.*

- Once the implant has been sufficiently exposed, seat the locking cap driver/ modular handle assembly into the gold locking screw. Turn the gold locking mechanism screw counter-clockwise until the teal locking cap can move freely. Do not rotate the gold cap more than 1.5 turns.
- Slide the teal locking cap using a forceps or other general surgical instrument to uncover all three bone screws (Figure 45).
- Seat the 2.0 mm hex driver/modular handle assembly into the exposed screw head.
- Ensure that the driver is fully seated in the screw head. Remove each screw by rotating the driver counter-clockwise. Repeat these steps until each screw has been removed. Ensure that the driver is on axis to the screw trajectory during screw removal.
- Attach the inserter guide or use a general surgical instrument to remove the implant through the surgical opening (Figure 46).

  Note: *Do not reuse an implant after removal.*

Kit Contents

Optio-C System Core Instrument Set: 07.01974.402

DESCRIPTION	QTY	PART NUMBER
Optio-C Screw, 12 mm, Variable, Self-tapping	6	07.01874.012
Optio-C Screw, 14 mm, Variable, Self-tapping	6	07.01874.014
Optio-C Screw, 16 mm, Variable, Self-tapping	6	07.01874.016
Optio-C Screw, 12 mm, Variable, Self-drilling	12	07.01875.012
Optio-C Screw, 14 mm, Variable, Self-drilling	12	07.01875.014
Optio-C Screw, 16 mm, Variable, Self-drilling	6	07.01875.016
Inserter Guide	1	07.01886.001
ATO Inserter Guide*	1	07.01887.001
Fixed Angle Guide	1	07.01888.001
Variable Angle Guide	1	07.01889.001
U-Joint Awl	1	07.01890.001
U-Joint Drill	1	07.01891.001
Straight Drill	2	07.01893.001
Straight Awl	1	07.01894.001
2.0 mm Straight Hex Driver	2	07.01895.001
Flexible Drill	1	07.01896.001
Flexible Awl	1	07.01897.001
2.0 mm Flexible Hex Driver	1	07.01898.001
Tamp	1	07.01899.001
Locking Cap Driver	2	07.01900.001
Torque Limiting Handle	1	07.01901.001
Modular Handle, Spin Cap	3	07.01902.001
Modular Handle, Impaction Cap	1	07.01903.001
U-Joint Sleeve, Tube	2	07.01904.001
U-Joint Sleeve, Tip	2	07.01905.001
Core Tray	1	07.01907.001
Screw Caddy Lid	1	07.01908.001
Screw Caddy	1	07.01909.001
2.0 mm U-Joint Hex Driver	1	07.01910.001
Distraction Pin, Single Prong	2	07.01911.001
Distraction Pin, Double Prong	2	07.01911.002
Distraction Pin Caddy	1	07.01912.001
Distraction Pin Caddy Lid	1	07.01913.001

Optio-C System Bone Prep Instrument Set: 07.01974.401

DESCRIPTION	QTY	PART NUMBER
Parallel Trial, 12 × 14 × 6 mm	1	07.01877.006
Parallel Trial, 12 × 14 × 7 mm	1	07.01877.007
Parallel Trial, 12 × 14 × 8 mm	1	07.01877.008
Parallel Trial, 12 × 14 × 9 mm	1	07.01877.009
Parallel Trial, 12 × 14 × 10 mm	1	07.01877.010
Parallel Trial, 12 × 14 × 11 mm	1	07.01877.011
Parallel Trial, 12 × 14 × 12 mm	1	07.01877.012
Parallel Rasp, 12 × 14 × 6 mm	1	07.01878.006
Parallel Rasp, 12 × 14 × 7 mm	1	07.01878.007
Parallel Rasp, 12 × 14 × 8 mm	1	07.01878.008
Parallel Rasp, 12 × 14 × 9 mm	1	07.01878.009
Implant Assembly Block	1	07.01884.001
Implant Assembly Tamp	1	07.01885.001
Modular Handle, Impaction Cap	4	07.01903.001
Bone Prep Tray	1	07.01906.001

** This instrument is optional and must be ordered separately.*

Optio-C System 14x16 Auxiliary Instrument Set: 07.01975.401

DESCRIPTION	QTY	PART NUMBER
Lordotic Trial, 14 × 16 × 6 mm	1	07.01879.026
Lordotic Trial, 14 × 16 × 7 mm	1	07.01879.027
Lordotic Trial, 14 × 16 × 8 mm	1	07.01879.028
Lordotic Trial, 14 × 16 × 9 mm	1	07.01879.029
Lordotic Trial, 14 × 16 × 10 mm	1	07.01879.030
Lordotic Trial, 14 × 16 × 11 mm	1	07.01879.031
Lordotic Trial, 14 × 16 × 12 mm	1	07.01879.032
Lordotic Rasp, 14 × 16 × 6 mm	1	07.01880.026
Lordotic Rasp, 14 × 16 × 7 mm	1	07.01880.027
Lordotic Rasp, 14 × 16 × 8 mm	1	07.01880.028
Lordotic Rasp, 14 × 16 × 9 mm	1	07.01880.029
Lordotic Rasp, 14 × 16 × 10 mm	1	07.01880.030
Lordotic Rasp, 14 × 16 × 11 mm	1	07.01880.031
Lordotic Rasp, 14 × 16 × 2 mm	1	07.01880.032
Auxiliary 14 × 16 Tray	1	07.01914.001

Optio-C System 15x18 Auxiliary Instrument Set: 07.01976.401

DESCRIPTION	QTY	PART NUMBER
Lordotic Trial, 15 × 18 × 6 mm	1	07.01879.046
Lordotic Trial, 15 × 18 × 7 mm	1	07.01879.047
Lordotic Trial, 15 × 18 × 8 mm	1	07.01879.048
Lordotic Trial, 15 × 18 × 9 mm	1	07.01879.049
Lordotic Trial, 15 × 18 × 10 mm	1	07.01879.050
Lordotic Trial, 15 × 18 × 11 mm	1	07.01879.051
Lordotic Trial, 15 × 18 × 12 mm	1	07.01879.052
Lordotic Rasp, 15 × 18 × 6 mm	1	07.01880.046
Lordotic Rasp, 15 × 18 × 7 mm	1	07.01880.047
Lordotic Rasp, 15 × 18 × 8 mm	1	07.01880.048
Lordotic Rasp, 15 × 18 × 9 mm	1	07.01880.049
Lordotic Rasp, 15 × 18 × 10 mm	1	07.01880.050
Lordotic Rasp, 15 × 18 × 11 mm	1	07.01880.051
Lordotic Rasp, 15 × 18 × 12 mm	1	07.01880.052

Visual Instrument Guide

Torque Limiting Handle	PART NUMBER
	07.01901.001

Modular Handle—Spin Cap	PART NUMBER
	07.01902.001

Modular Handle—Impaction Cap	PART NUMBER
	07.01903.001

Distraction Pins	PART NUMBER
Single Prong	07.01911.001
Double Prong	07.01911.002

Implant Trials—Parallel and Lordotic	PART NUMBER
Parallel Trial 12 × 14, 6-12 mm (1 mm increments)	07.01877.006-07.01877.012
Parallel Trial 14 × 16, 6 mm	07.01877.026
Parallel Trial 15 × 18, 6 mm	07.01877.046
Lordotic Trial 12 × 14, 6-12 mm (1 mm increments)	07.01879.006-07.01879.012

Implant Rasps—Parallel and Lordotic	PART NUMBER
Parallel Rasp 12 × 14, 6-12 mm (1 mm increments)	07.01878.006-07.01878.012
Parallel Rasp 14 × 16, 6 mm	07.01878.026
Parallel Rasp 15 × 18, 6 mm	07.01878.046
Lordotic Rasp 12 × 14, 6-12 mm (1 mm increments)	07.01880.006-07.01880.012

Inserter Guide	PART NUMBER
	07.01886.001

ATO Inserter Guide* (optional)	PART NUMBER
	07.01887.001

Fixed Angle Guide	PART NUMBER
	07.01888.001

** Must be ordered separately.*

Variable Angle Guide	PART NUMBER
	07.01889.001

Tamp	PART NUMBER
	07.01899.001

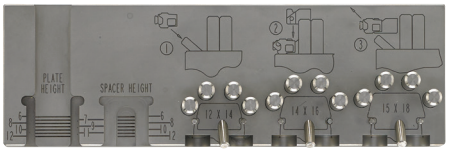
Locking Cap Driver	PART NUMBER
	07.01900.001

U-Joint Instruments	PART NUMBER
U-Joint Awl	07.01890.001
U-Joint Drill	07.01891.001
U-Joint 2.0 mm Hex Driver	07.01910.001

	PART NUMBER
U-Joint Sleeve Tube	07.01904.001
U-Joint Sleeve Tip	07.01905.001

Straight Instruments	PART NUMBER
Straight Awl	07.01894.001
Straight Drill	07.01893.001
Straight 2.0 mm Hex Driver	??

Flexible Instruments	PART NUMBER
Flexible Awl	07.01897.001
Flexible Drill	07.01896.001
Flexible 2.0 mm Hex Driver	07.01898.001



Implant Assembly Block	PART NUMBER
	07.01884.001

Implant Assembly Tamp	PART NUMBER
	07.01885.001

Important Information on the Optio-C Anterior Cervical PEEK Interbody System

Description

The Optio-C System is composed of one Optio-C PEEK IBF spacer, one Optio-C anterior cervical plate, and three Optio-C bone screws. The Optio-C device is secured by an antimigration system that is designed to maintain no profile. The Optio-C System is designed to maximize fusion with a load-sharing interface and multiple implant footprints.

Indications

The Optio-C anterior cervical Intervertebral Body Fusion Device (IBFD) is indicated for stand-alone anterior cervical interbody fusion procedures in skeletally mature patients with cervical degenerative disc disease at one level from C2 to T1. Degenerative disc disease (DDD) is defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The Optio-C IBFD is composed of one Optio-C PEEK IBF spacer, one Optio-C anterior cervical plate, and three Optio-C bone screws.

The Optio-C IBFD is to be used with autograft and implanted via an open, anterior approach in patients who have had six weeks of nonoperative treatment.

Contraindications

- Disease conditions that have been shown to be managed safely and predictably without the use of internal fixation devices are relative contraindications to the use of these devices.
- Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
- Severe osteoporosis is a relative contraindication because it can increase the occurrence of subsidence.
- Any entity or condition that totally precludes the possibility of fusion, such as cancer, kidney dialysis or osteopenia, is a relative contraindication.
- Obesity.
- Pregnancy.
- Certain degenerative disease.
- Foreign body sensitivity.
- The patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant.
- Metabolic disorders that can impair bone formation.
- Inadequate bone stock to support the device.
- Poor prognosis for good wound healing (e.g., decubitis ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).
- Known patient sensitivity to device materials (titanium alloy, Ti-6Al-4V ELI or polyetheretherketone [PEEK]) .
- Use in the posterior elements (pedicles) of the cervical, thoracic or lumbar vertebrae.
- Where attempted correction exceeds the limits of physiological conditions.
- Any condition not described in the indications for use.

See also the WARNINGS and PRECAUTIONS section of this document.

Materials

Implants: The Optio-C plate and bone screws are manufactured from titanium alloy (Ti-6Al-4V ELI) per ASTM F-136. The Optio-C anterior cervical PEEK Intervertebral Body Fusion (IBF) spacer is manufactured from polyetheretherketone (PEEK) per ASTM F2026. Since PEEK is radiolucent, the PEEK IBF devices contain radiographic markers composed of titanium alloy (Ti-6Al-4V ELI) per ASTM F-136.

Instruments: The Optio-C System instrumentation is made from medical/surgical grade stainless steel, plastic, aluminum, and silicone.

Do not use any of the Optio-C System components with the components from any other system or company unless stated in this document.

Warnings

- Implants and instruments should be stored in their original packaging in a dry environment, away from aggressive or oily chemicals.
- When inserting the implant, care should be taken to avoid using excessive force, which has the potential to cause damage to the implant or surrounding tissue.
- When preparing the disc space, care should be taken to ensure that an appropriate amount of bone is removed; excessive removal of bone has the potential to cause subsidence, while failing to remove enough bone has the potential to cause poor fusion.
- During screw insertion, care should be taken to avoid bone screw stripping, which has the potential to cause an unstable screw construct.
- Care should be taken when handling the flexible instruments. Specifically, the flexible tip should be maintained in the guide to prevent soft tissue damage.
- When inserting the implant, ensure a tight fit between the inserter and implant. Release distraction before drilling to prevent shifting.
- During distraction of the disc space, care should be taken to prevent over-distraction or under-distraction, which has the potential to cause irreversible damage to the patient or an unstable implant construct.
- If existing hardware is present, compatibility between the distraction pin and the existing hardware should be verified before use. When the distraction pin is used with existing hardware, extreme care should be taken to prevent damage to existing hardware.
- Potential risks identified with the use of this device system, which may require additional surgery, include:
  - Device component fracture
  - Loss of fixation
  - Non-union
  - Neurological injury
  - Vascular or visceral injury
  - Do not use this product for other than labeled indications (off-label use).
- Components of competitive spinal systems should not be used with the Optio-C devices.
- Patient selection shall consider the following factors which are important to the success of the procedure and the performance of the device:
  - The patient's weight. An overweight or obese patient can produce loads on the device that can lead to a loss of interbody height or failure of the device and/or the operation.

Important Information on the Optio-C Anterior Cervical PEEK Interbody System *(continued)*

- The patient's occupation or activity. If the patient is involved in an occupation or activity that includes substantial walking, running, lifting or muscle strain, the resultant forces can cause loss of disc height and/or failure of the device.
- A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.
- Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary relief.
- Foreign body sensitivity. If material sensitivity is suspected, appropriate tests should be made before material selection or implantation.
- Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures in which bone graft is used.

- Implants can break when subjected to the increased loading associated with delayed union or non-union. Spinal implants are loadsharing devices that are used to obtain an alignment until normal healing occurs. If healing is delayed or does not occur, the implant may eventually break because of fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks of implant failure.
- These warnings do not include all adverse effects that can occur with surgery in general. General surgical risks should be explained to the patients before surgery.
- The Optio-C anterior cervical Intervertebral Body Fusion Device (IBFD) is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
- The Optio-C PEEK IBF spacer is not to be used alone.
- The Optio-C anterior cervical plate is not to be used alone.

Precautions

It is strongly recommended that the patient be informed of the risks associated with surgical procedures and components.

- Surgical implants must never be reused. An explanted implant should never be reimplanted. Although the device appears undamaged, it may have small defects and internal stress patterns that could lead to early breakage. Reuse of a singleuse device that has contacted blood, bone, tissue or other body fluids can lead to patient or user injury. Risks associated with reuse of singleuse devices include:
  - Mechanical malfunction
  - Transmission of infectious agents
- Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, or other patient conditions that can affect the performance of the system.
- Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are two of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in fracture. The patient should understand that an implant is not as

strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

- The Optio-C IBFD device should be used only after the spinal surgeon has had training in this method of fixation and has become thoroughly knowledgeable about the spinal anatomy and biomechanics.
- The Surgical Technique Guide is not a substitute for training; it is for informational purposes only.
- Carefully read all instructions and be familiar with the Optio-C Anterior Cervical PEEK Interbody System surgical technique before use.

For more information, visit ZimVie.com

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