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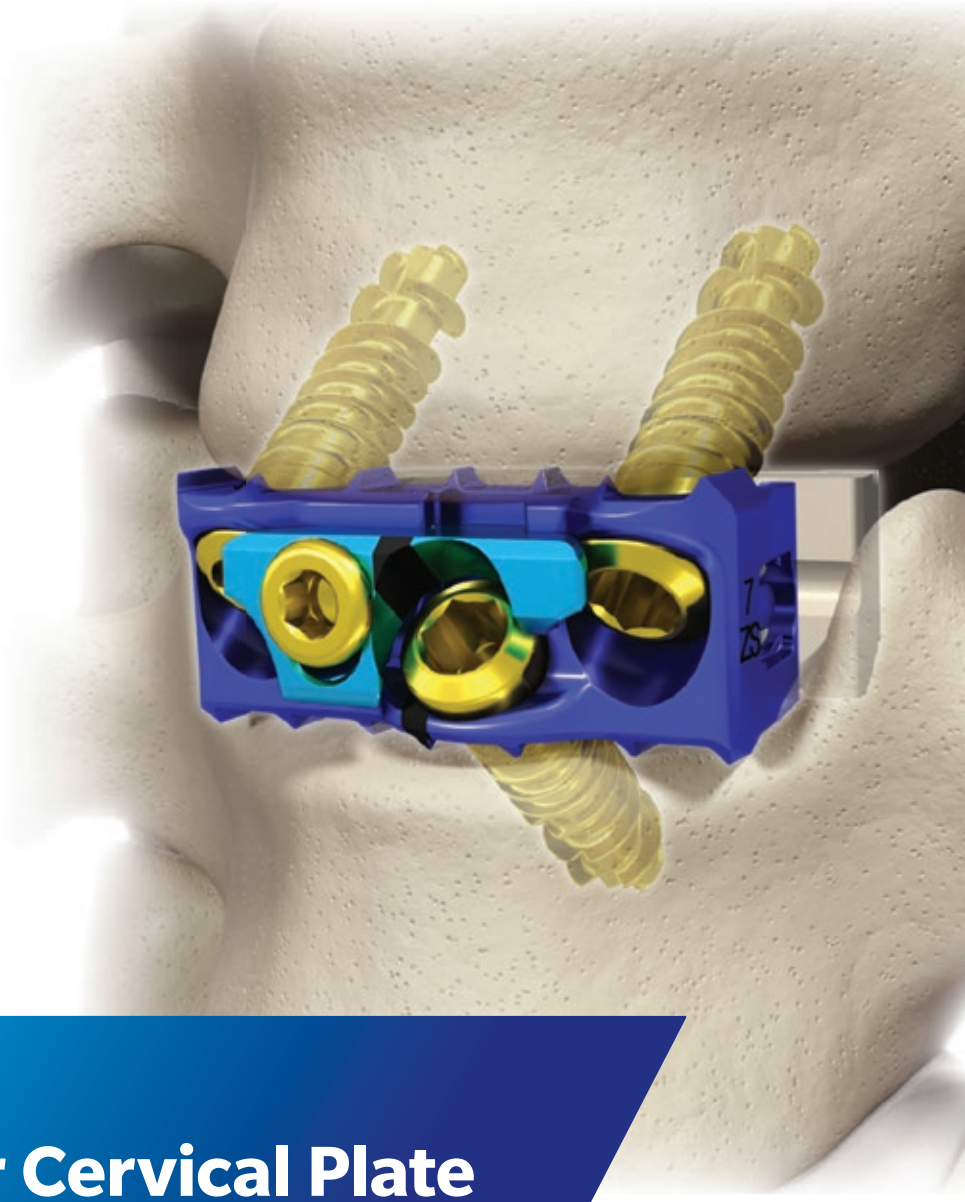


Cervical Solutions

Optio-C® Anterior Cervical Plate
with Allograft/Autograft

Surgical Technique Guide

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

Optio-C Anterior Cervical Plate with Allograft/Autograft
Surgical Technique

Global Availability

Some instruments and/or implants may not be available in some geographic regions.

Check with local representation for product availability.

Optio-C System Overview

The Optio-C System is composed of one Optio-C Anterior Cervical Plate and three Optio-C bone screws, and is designed for use with one of the following: (1) one Optio-C structural allograft or (2) one structural allograft/autograft of the same height as the Optio-C Plate. The Optio-C Plate and Allograft are used to provide structural stability in skeletally mature individuals following discectomy and are offered in multiple contours, lordotic angles, footprints and heights to accommodate variations in cervical anatomy.

Optio-C Plates

The Optio-C Plate is a component of the Optio-C Anterior Cervical System and is intended to be used only in anterior surgical procedures. The Optio-C Plate must be used with three Optio-C bone screws and is designed to be used with either one of the following:

- One Optio-C structural allograft **or**
- One structural allograft/autograft of the same height as the plate

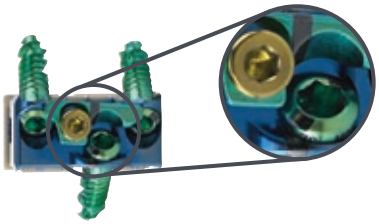
The Optio-C Plate and structural allograft are supplied sterile to the end user. The bone screws and instrumentation are supplied non sterile and are intended to be sterilized by the end user.

The Optio-C Plate is offered in a one-level configuration, with a standard width and multiple heights, and is designed to facilitate fusion. The plate with a structural allograft/autograft is placed in the cervical disc space, flush with the adjacent vertebral bodies. Bone screws pass through the screw holes of the plate and affix to bone to help prevent implant migration. The implant construct can be implanted in two orientations: standard orientation, two screws cephalad and one screw caudal, or inverted orientation, one screw cephalad and two screws caudal.

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 to prevent screw migration. The plate midline is indicated by a black stripe on the anterior face of the plate.

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



Optio-C Allograft

The Optio-C Plate and Allograft 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 × width) including plate depth connected to the Optio-C Allograft. Optio-C Allograft is provided sterile.

Optio-C Allograft is available in heights from 6 mm to 12 mm, in Lordotic (6°) and Parallel (0°).

Lordotic

Description (L × W × H, Degrees)	Item#
12 × 14 × 6–12 mm, 6°	07.01852.006–012
14 × 16 × 6–12 mm, 6°	07.01853.006–012
15 × 18 × 6–12 mm, 6°	07.01854.006–012

Parallel

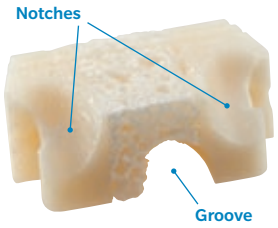
Description (L × W × H, Degrees)	Item#
12 × 14 × 6–12 mm, 0°	07.01849.006–012
14 × 16 × 6–12 mm, 0°	07.01850.006–012
15 × 18 × 6–12 mm, 0°	07.01851.006–012

Lordotic

Parallel

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

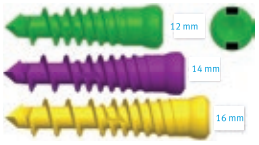
For the lordotic allograft, the anterior height is equal to the size specified, and the posterior height is approximately 1 mm smaller (e.g., for a 7 mm Optio-C lordotic allograft, the posterior height is 6 mm).



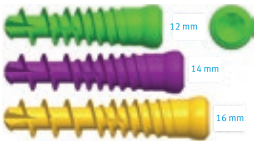
Optio-C Screws

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 they are color coded by length. Optio-C screws provide a lag effect to ensure the interbody device fits snugly to the anatomy.

Self-drilling screws may reduce the surgical steps required to penetrate the cortex of the vertebral body and 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

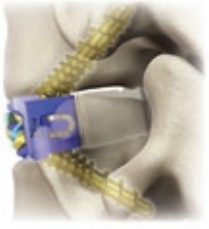
Optio-C System Plates and Screws allow for variable angle placement as follows:

- 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 1 mm from the plate midline, and it angles 5° medial toward midline.

The Optio-C Plate and Allograft can be implanted in two orientations:

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

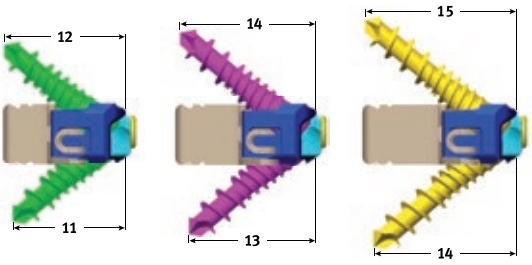


Standard

Inverted

Optio-C Screw Length

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



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

Surgical Technique

Option 1: Optio-C Structural Allograft

Inserter Guide

Pre-operative Planning and Patient Positioning

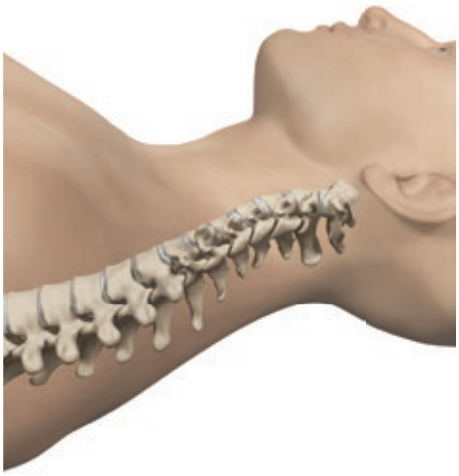


Fig. 1 ▲

Step 1

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. (Fig. 1)

Exposure, Location and Site Preparation

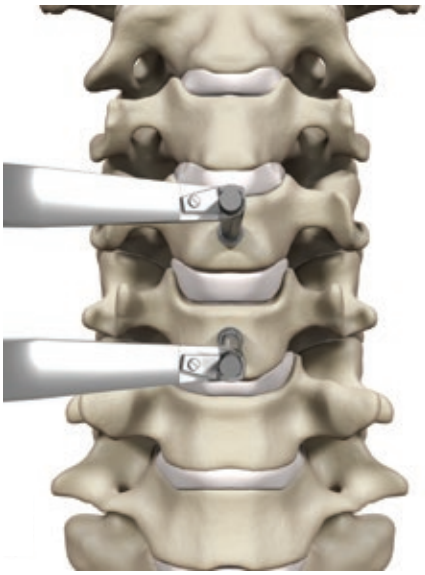


Fig. 2 ▲

Step 2

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. (Fig. 2)

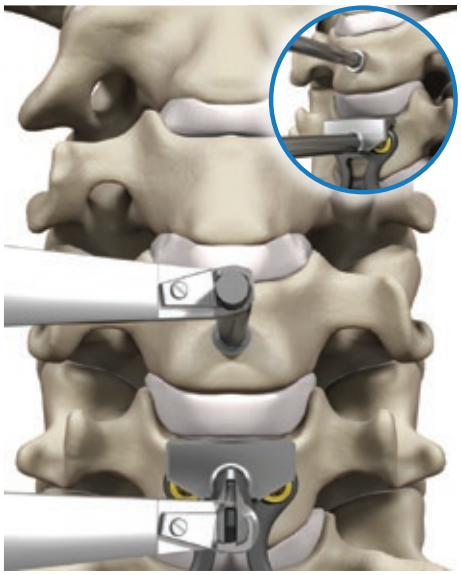


Fig. 3 ▲

Step 3

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. (Fig. 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.*

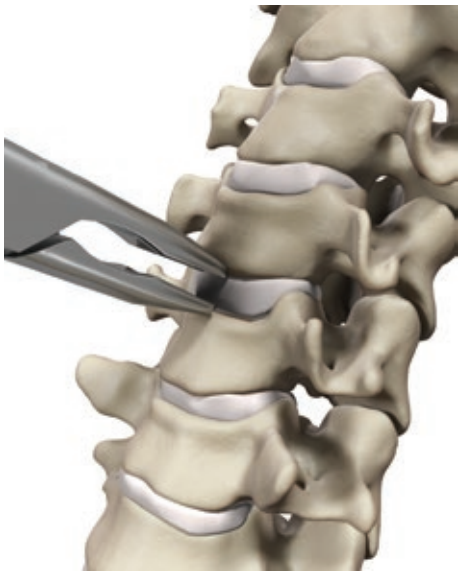


Fig. 4 ▲

Step 4

Prepare the anatomy to accommodate placement of the Optio-C Plate. It is recommended to insert the Optio-C Plate under distraction. (Fig. 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.*

Implant Sizing

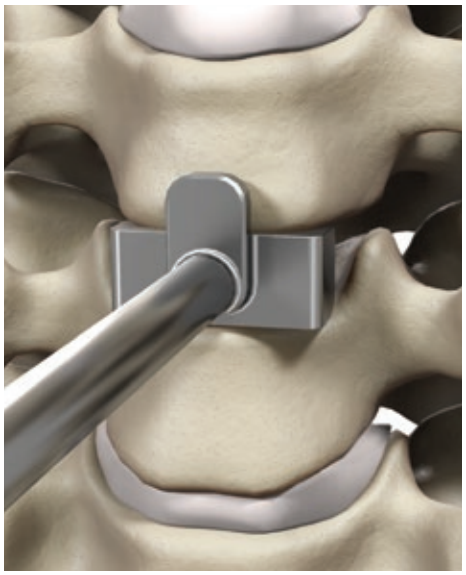


Fig. 5 ▲

Step 5

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 plate footprint by using the Trials and Rasps (12 × 14, 14 × 16, or 15 × 18). These instruments equal the shape of the assembled implant (plate + Optio-C Allograft). (Fig. 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.*

Instruments

Distraction Pins
07.01911.001 Single Prong
07.01911.002 Double Prong

Modular Handle—
Impaction Cap
07.01903.001

Implant Trials—
Parallel and Lordotic
07.01877.006 – 012, .026, .046
07.01879.006 – 012

Implant Rasps—
Parallel and Lordotic
07.01878.006 – 012, .026, .046
07.01880.006 – 012

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

Implant Assembly

Fig. 6 ▲

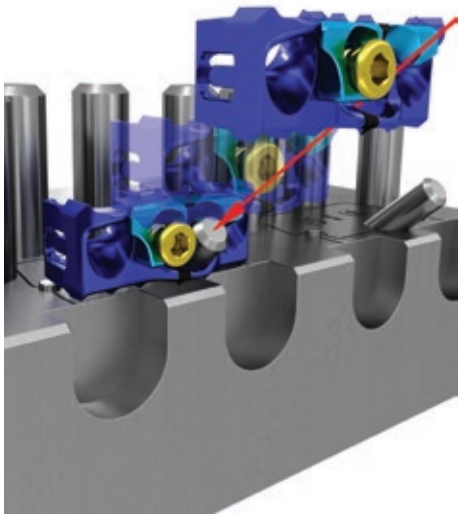


Fig. 7 ▲

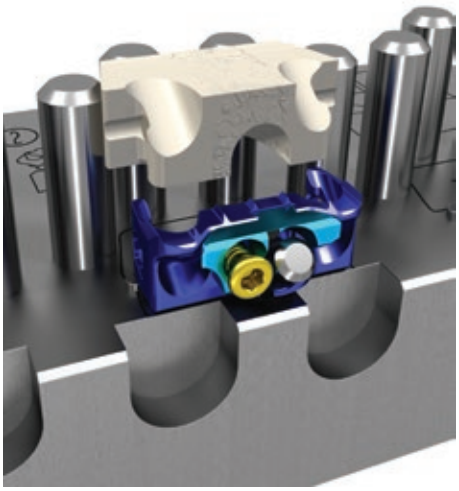


Fig. 8 ▲

Step 6

The Optio-C implant must be assembled before use. (Fig. 6)

Confirm the chosen implant sizes and then remove the Optio-C Plate and Optio-C Allograft from their sterile packaging.

Place the Optio-C Allograft into a sterile container and rehydrate with sterile water, sterile saline or the patient's blood. Rehydrate for at least 30 seconds before assembly with the plate.

NOTE: *Optio-C Plate height and Optio-C Allograft height must match. For example, if the 7 mm Trial fits appropriately, then a 7 mm plate and 7 mm allograft are used.*

NOTE: *The sizing scale on the Implant Assembly Fixture can be used to confirm implant sizes before assembly.*

Step 7

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. (Fig. 7)

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

Step 8

Before connecting the rehydrated allograft to the plate, ensure that the notches for the lateral screws are facing upward. Place the allograft into the Implant Assembly Block behind the plate between the four alignment pins. (Fig. 8)

Instruments

Implant Assembly Block
07.01884.001

Attaching Implant

Fig. 9 ▲

Step 9

Use the Implant Assembly Tamp to connect the allograft to the plate until an audible click is heard. (Fig. 9)

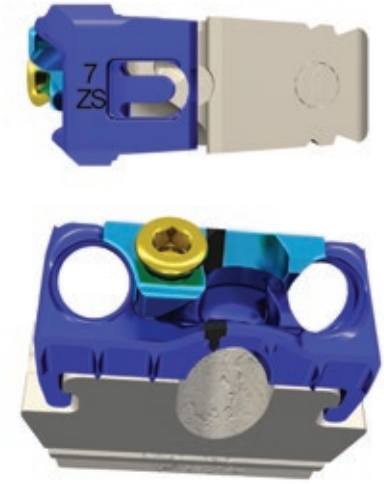


Fig. 10 ▲

Step 10

Confirm visually that the implant is assembled appropriately. Ensure that the plate and allograft sizes match and that the plate screw holes and allograft notches are aligned. (Fig. 10)

NOTE: *The Optio-C Implant can be loaded onto either Optio-C Inserter Guide directly from the Implant Assembly Block.*

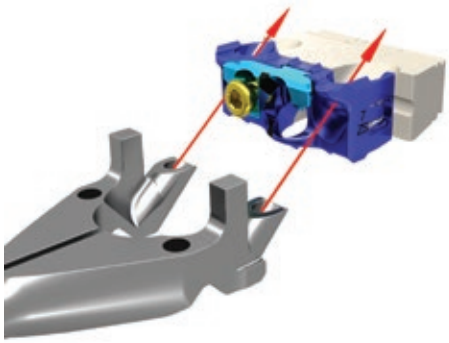


Fig. 11 ▲

Step 11

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. (Fig. 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).*

Instruments

Implant Assembly Block
07.01884.001

Modular Handle—
Impaction Cap
07.01903.001

Implant Assembly Tamp
07.01885.001

Inserter Guide
07.01886.001

Implant Placement

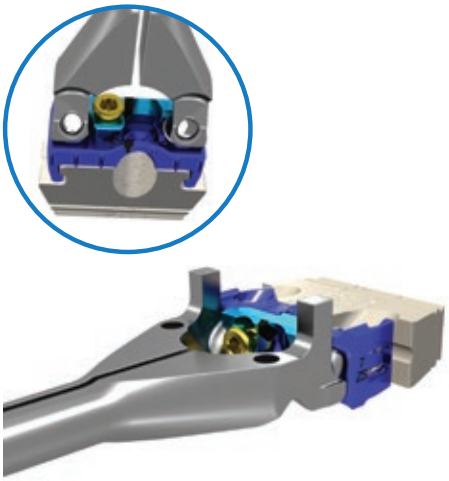


Fig. 12 ▲

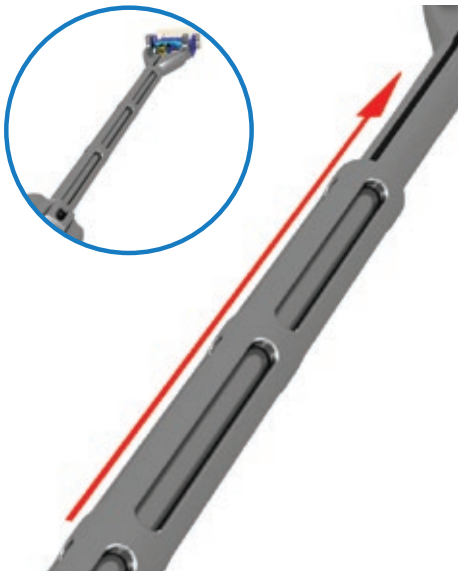


Fig. 13 ▲

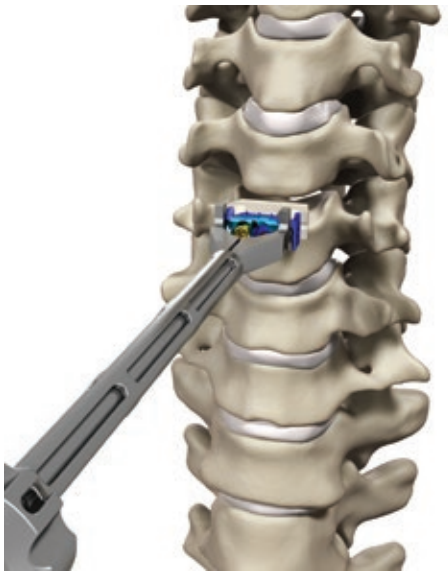


Fig. 14 ▲

Step 12

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. (Fig. 12)

Step 13

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. (Fig. 13)

Step 14

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. (Fig. 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.*

Instruments

Inserter Guide
07.01886.001

Modular Handle—
Impaction Cap
07.01903.001

Lateral Screw Hole Preparation / Screw Placement

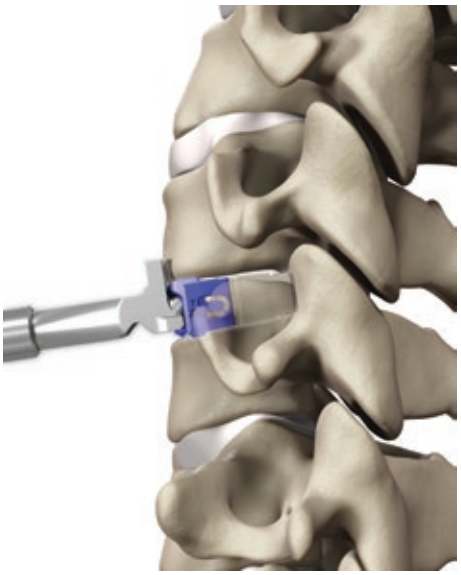


Fig. 15 ▲

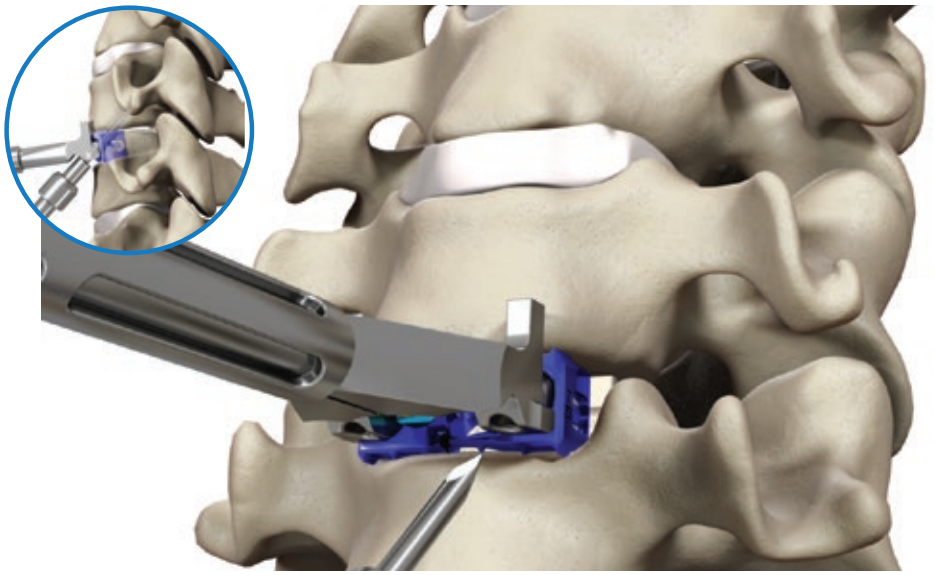


Fig. 16 ▲

Step 15

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. (Fig. 15)

NOTE: *If using the Distraction Pin, remove the Distraction Pin with the Caspar Distractor.*

Step 16

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. (Fig. 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.*

Instruments

Modular Handle—
Spin Cap
07.01902.001

Awls
07.01894.001 Straight
07.01897.001 Flexible
07.01890.001 U-Joint

Drills
07.01893.001 Straight
07.01896.001 Flexible
07.01891.001 U-Joint

Modular Handle—
Impaction Cap
07.01903.001

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

Midline Screw Hole Preparation/ Screw Placement

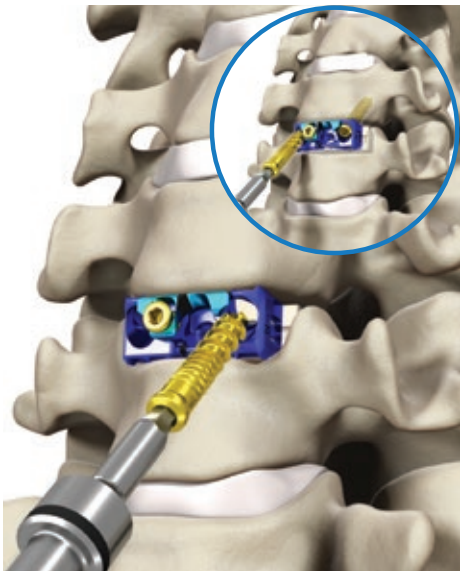


Fig. 17 ▲

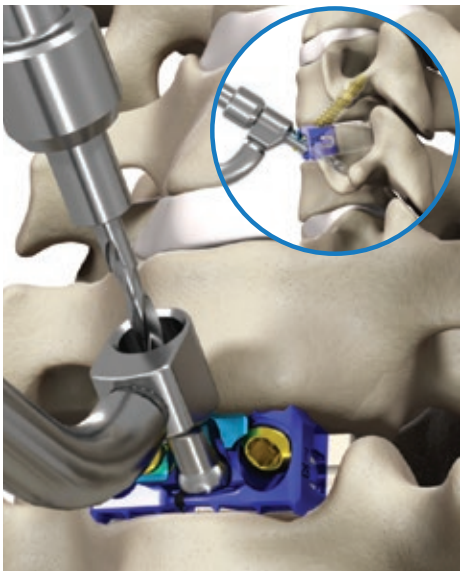


Fig. 18 ▲

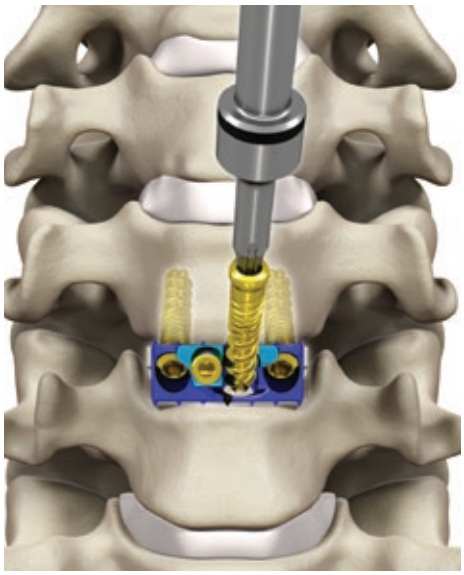


Fig. 19 ▲

Step 17

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. (Fig. 17)

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

Step 18

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. (Fig. 18)

Step 19

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 provisionally. Ensure that the Driver is on axis to the prepared screw trajectory during screw insertion and final tightening. (Fig. 19)

Instruments

Modular Handle—
Spin Cap
07.01902.001

2.0 mm Hex Drivers
07.01895.001
Straight
07.01898.001
Flexible
07.01910.001
U-Joint

Guides
07.01888.001
Fixed Angle (gold end)
07.01889.001
Variable Angle
(silver end)

Awls
07.01894.001
Straight
07.01897.001
Flexible
07.01890.001
U-Joint

Drills
07.01893.001
Straight
07.01896.001
Flexible
07.01891.001
U-Joint

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

Final Tightening of Bone Screws

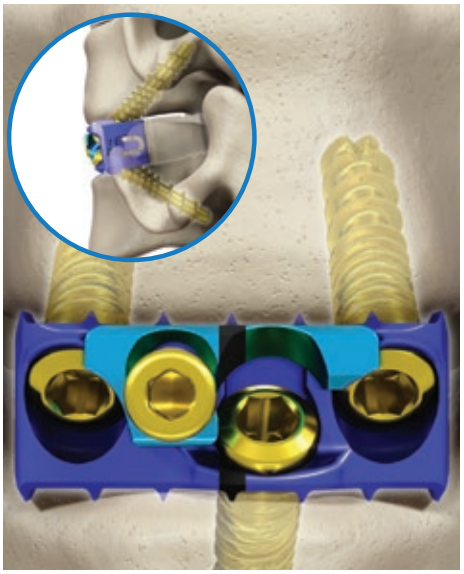


Fig. 20 ▲

Step 20

Completely engage the 2.0 mm Hex Driver in each screw head and fully seat all bone screws. (Fig. 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.*

Securing the Locking Cap

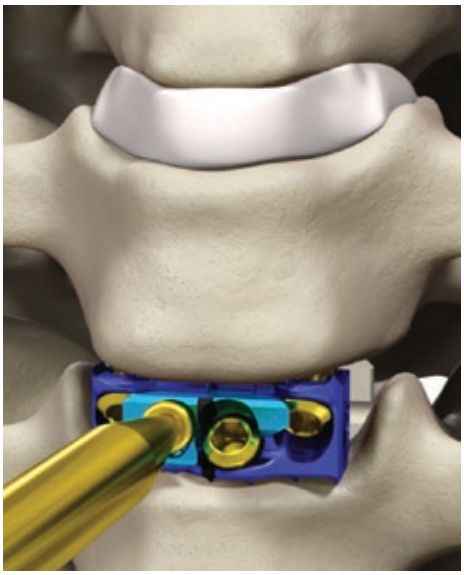


Fig. 21 ▲

Step 21

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. (Fig. 21)

Fig. 22 ▲

Step 22

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. (Fig. 22)

Instruments

Torque Limiting Handle
07.01901.001

Locking Cap Driver
07.01900.001

Surgical Technique

Option 1: Optio-C Structural Allograft

ATO Inserter Guide (Optional)

Planning, Positioning and Exposure

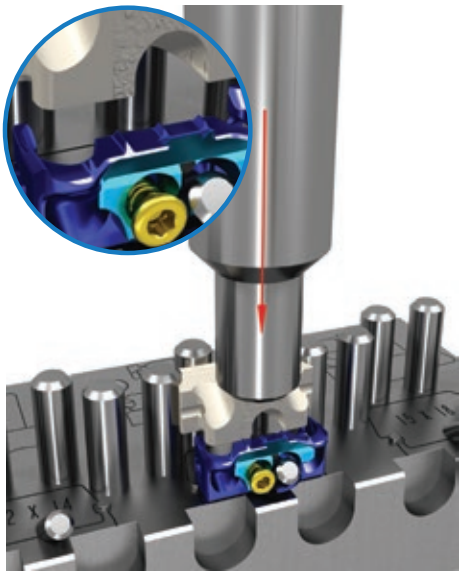


Fig. 23 ▲

Step 1

Repeat step 1, Pre-Operative Planning, through step 10, Implant Assembly, on pages 6–9. (Fig. 23)

Attaching the Implant to the ATO Inserter Guide

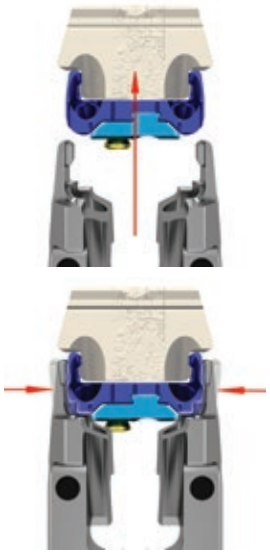


Fig. 24 ▲

Step 2

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. (Fig. 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.* (Fig. 24, bottom)

Instruments

Modular Handle—
Impaction Cap
07.01903.001

ATO Inserter Guide
07.01887.001
Optional instrument. Available upon request.

Implant Placement

Fig. 25 ▲

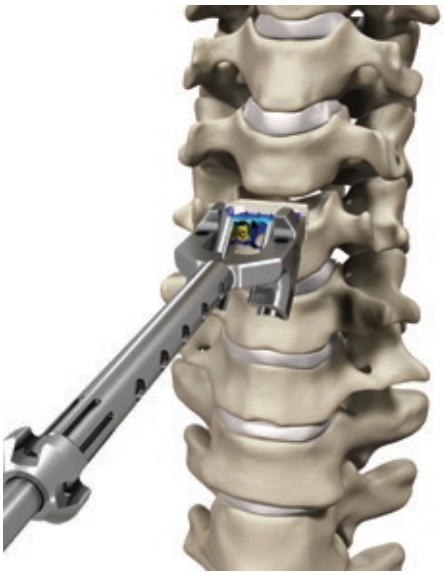


Fig. 26 ▲

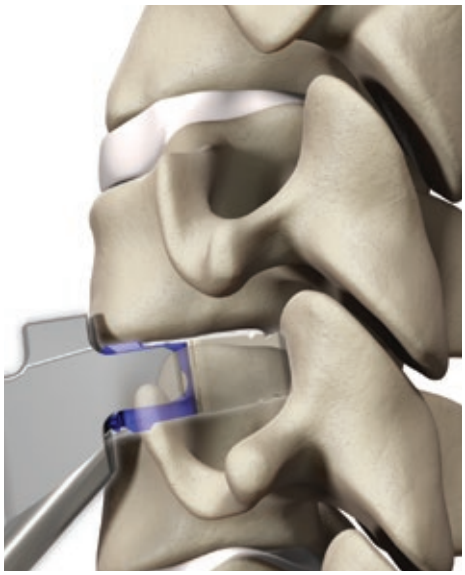


Fig. 27 ▲

Step 3

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. (Fig. 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. (Fig. 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 allograft.*

Step 4

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

Step 5

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. (Fig. 27)

Instruments

Modular Handle—
Impaction Cap
07.01903.001

ATO Inserter Guide
07.01887.001
Optional instrument. Available upon request.

Lateral Screw Hole Preparation/ Screw Placement

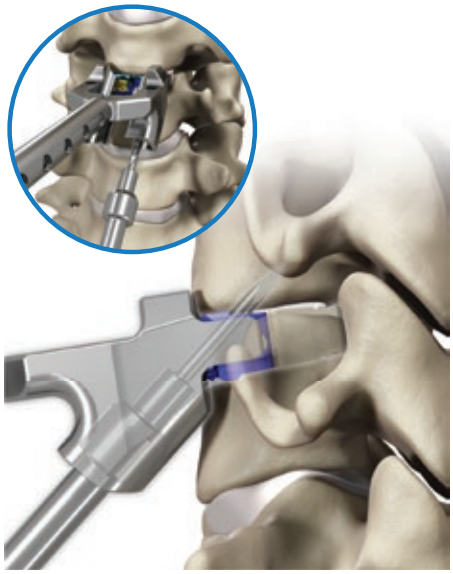


Fig. 28 ▲

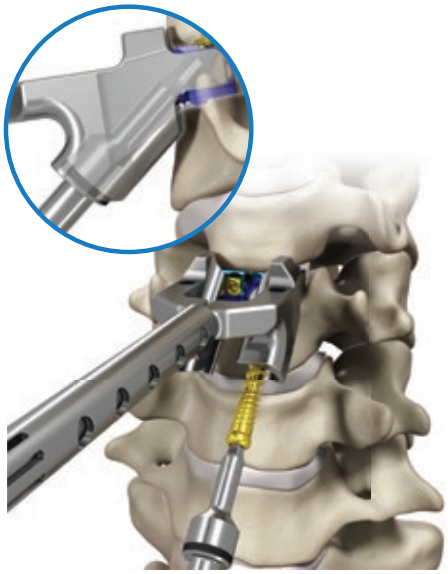


Fig. 29 ▲

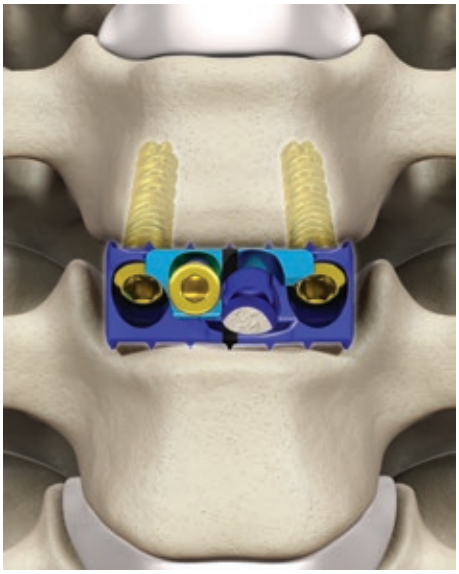


Fig. 30 ▲

Step 6

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. (Fig. 28)

Step 7

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. (Fig. 29)

The Driver laser marking approaches the edge of the guide tube to indicate the screw is nearly seated. (Fig. 29, inset)

Step 8

Repeat step 7 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. (Fig. 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.*

Instruments

Modular Handle—
Spin Cap
07.01902.001

Awls
07.01894.001 Straight
07.01897.001 Flexible

Drills
07.01893.001 Straight
07.01896.001 Flexible

2.0mm Hex Drivers
07.01895.001 Straight
07.01898.001 Flexible

Midline Screw Hole Preparation/ Screw Placement

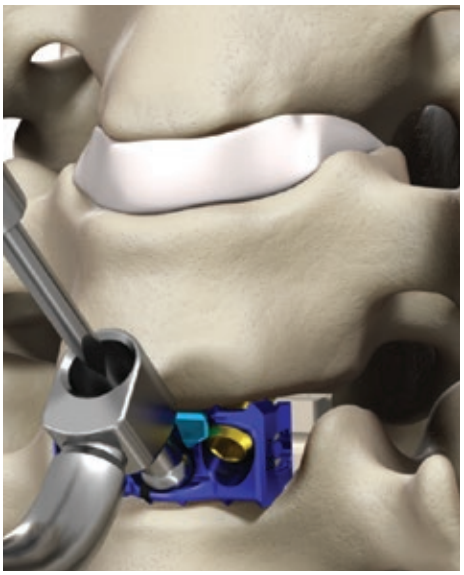


Fig. 31 ▲

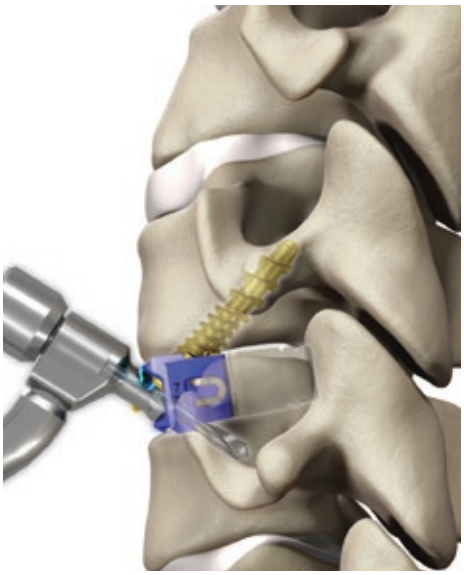


Fig. 32 ▲

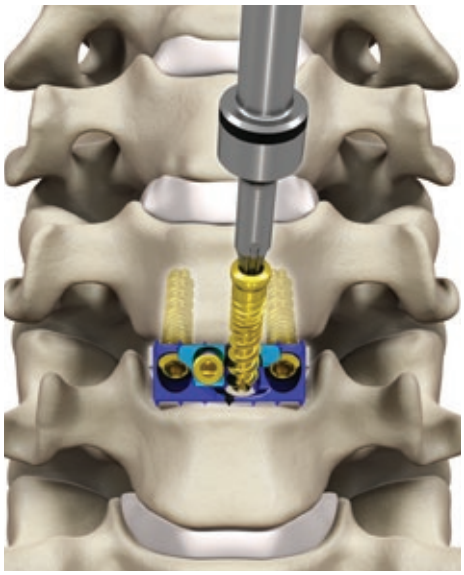


Fig. 33 ▲

Step 9

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. (Fig. 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. (Fig. 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.*

Step 10

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. (Fig. 33)

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

Instruments

Guides
07.01888.001
Fixed Angle (gold end)
07.01889.001
Variable Angle (silver end)

Modular Handle—
Spin Cap
07.01902.001

Awls
07.01894.001
Straight
07.01897.001
Flexible
07.01890.001
U-Joint

Drills
07.01893.001
Straight
07.01896.001
Flexible
07.01891.001
U-Joint

2.0 mm Hex Drivers
07.01895.001
Straight
07.01898.001
Flexible
07.01910.001
U-Joint

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

Final Tightening of Bone Screws:

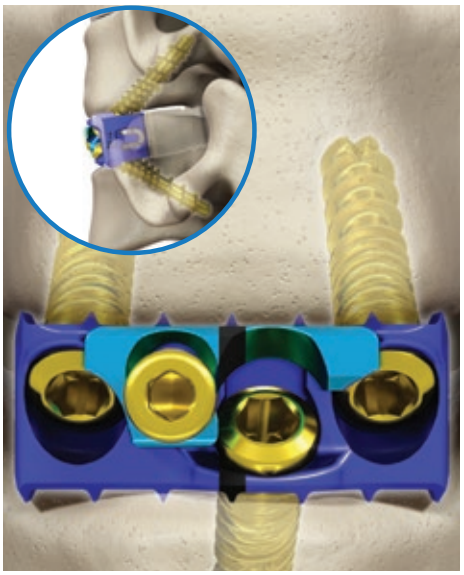


Fig. 34 ▲

Step 11

Completely engage the Driver in each screw head and fully seat all bone screws. (Fig. 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.*

Securing the Locking Cap

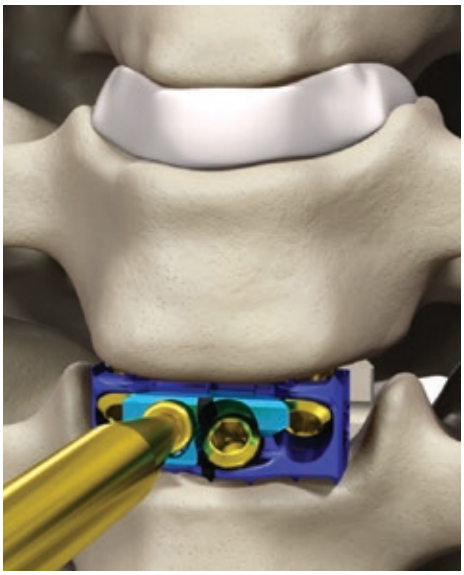


Fig. 35 ▲

Step 12

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. (Fig. 35)

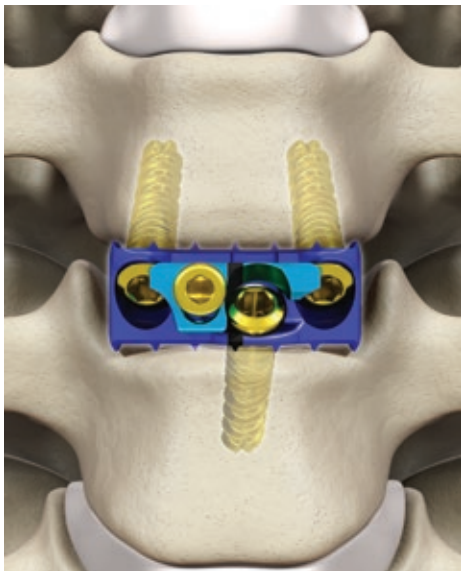


Fig. 36 ▲

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. (Fig. 36)

Instruments

Torque Limiting Handle
07.01901.001

Locking Cap Driver
07.01900.001

Surgical Technique

Option 1: Optio-C Structural Allograft

Freehand Screw Insertion

Planning, Positioning and Exposure

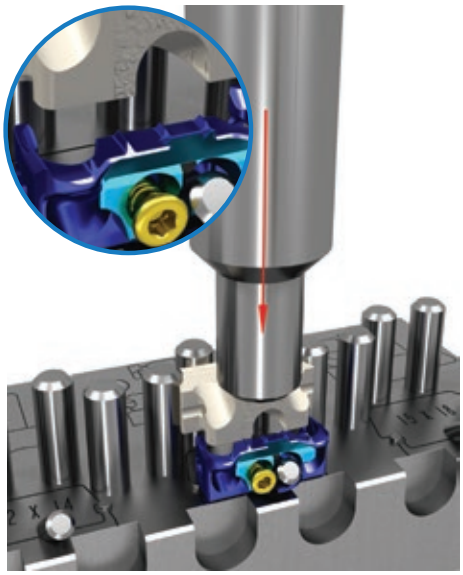


Fig. 37 ▲

Step 1

Repeat step 1, Pre-operative Planning, through step 13, Attaching the Implant to the Inserter, on pages 6–10. (Fig. 37)

Implant Insertion

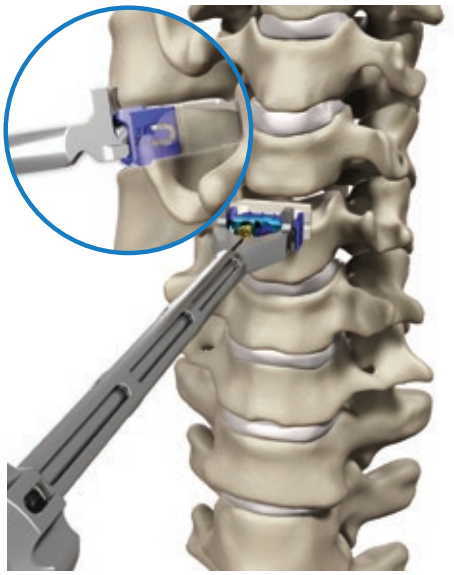


Fig. 38 ▲

Step 2

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. (Fig. 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.*

Instruments

Modular Handle—
Impaction Cap
07.01903.001

Inserter Guide
07.01886.001

Screw Hole Preparation/ Screw Placement

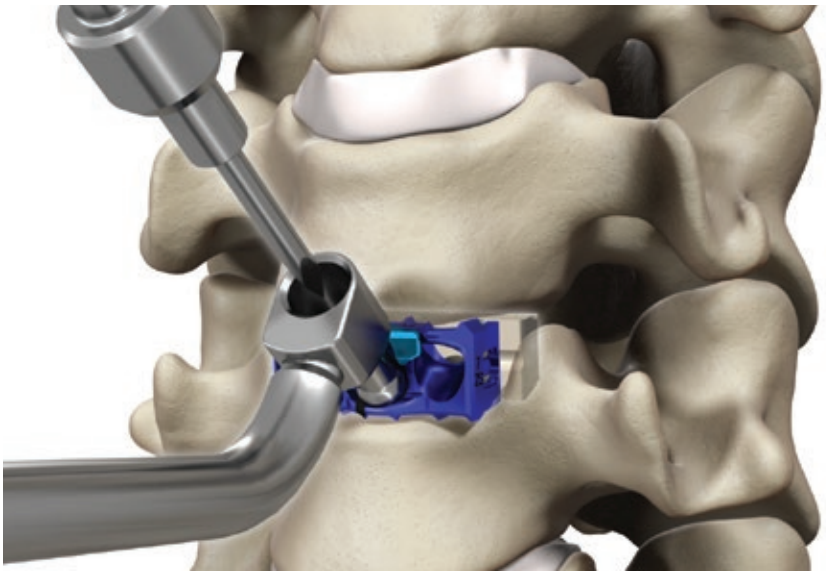


Fig. 39 ▲

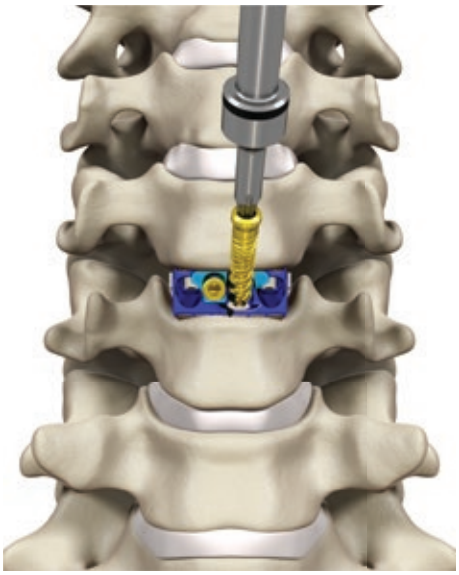


Fig. 40 ▲

Step 3

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. (Fig. 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.*

Step 4

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. (Fig. 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.*

Instruments

Modular Handle—
Spin Cap
07.01902.001

Awls
07.01894.001
Straight
07.01897.001
Flexible
07.01890.001
U-Joint

Drills
07.01893.001
Straight
07.01896.001
Flexible
07.01891.001
U-Joint

Guides
07.01888.001
Fixed Angle (gold end)
07.01889.001
Variable Angle
(silver end)

2.0 mm Hex Drivers
07.01895.001
Straight
07.01898.001
Flexible
07.01910.001
U-Joint

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

Tamp (optional)
07.01899.001

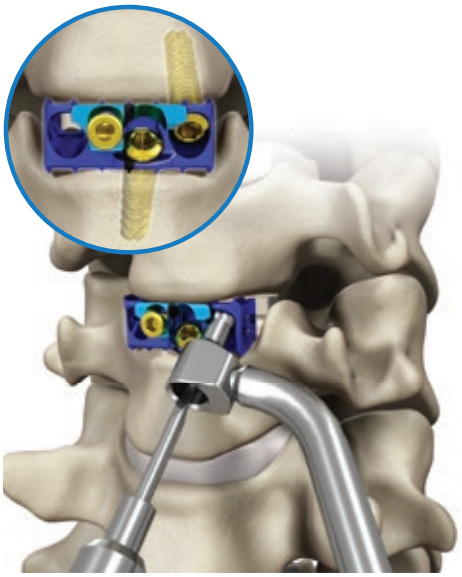


Fig. 41 ▲

Step 5

Repeat these steps for the lateral screws, using the same "drill-and-fill" technique. (Fig. 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.*

Final Tightening of Bone Screws

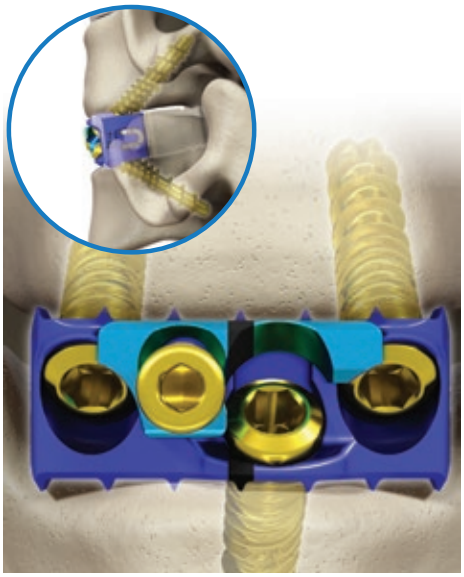


Fig. 42 ▲

Step 6

Completely engage the 2.0 mm Hex Driver in each screw head, and fully seat all bone screws. (Fig. 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

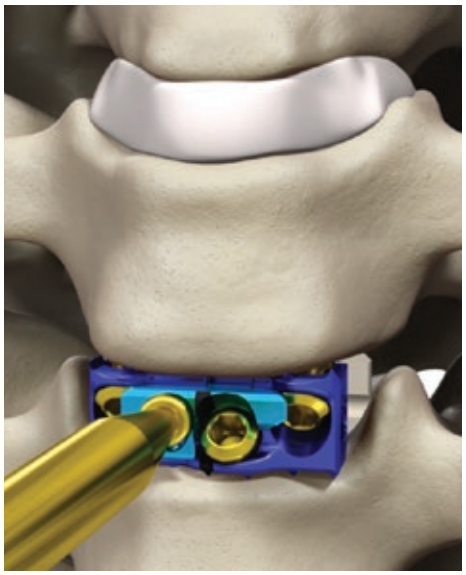


Fig. 43 ▲

Step 7

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. (Fig. 43)

Instruments

Modular Handle—
Spin Cap
07.01902.001

2.0 mm Hex Drivers
07.01895.001 Straight
07.01898.001 Flexible
07.01910.001 U-Joint

Locking Cap Driver
07.01900.001

Torque Limiting Handle
07.01901.001

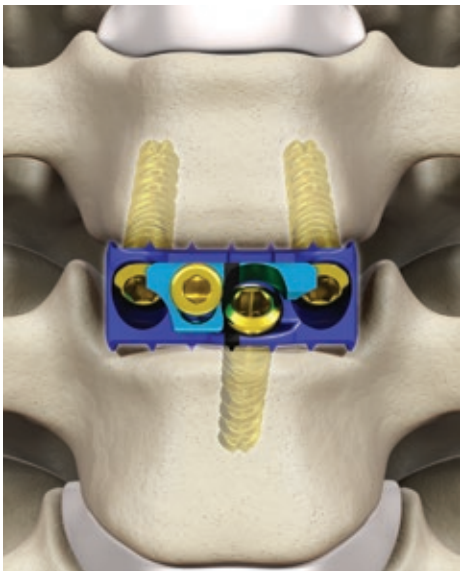


Fig. 44 ▲

Step 7 *(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. (Fig. 44)

Surgical Technique

Option 2: Structural Allograft/ Autograft of the Same Height as the Optio-C Plate

Inserter Guide

Description

The Optio-C Plate can also be used with an Optio-C Allograft or a structural allograft/ autograft of the same height as the Optio-C Plate. The structural allograft/autograft width selection is specifically chosen to fit within the lateral walls of the Optio-C plate. The decision whether to use an Optio-C Allograft or a structural allograft/autograft is based on surgeon preference; both options are appropriate for use with the stated indications.

The surgeon must exercise his/her best judgment to prevent interference with the Optio-C plate and screws based on the position of the structural allograft/autograft, which is also in the intervertebral space.

Pre-Operative Planning and Patient Positioning

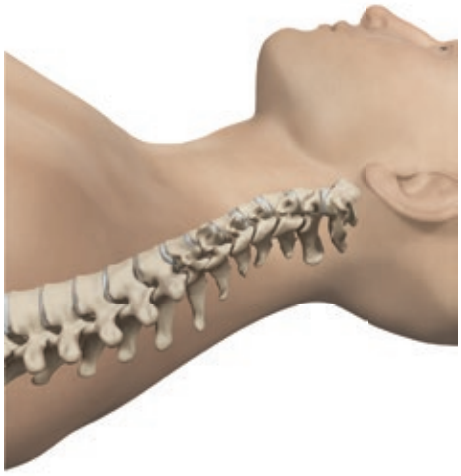


Fig. 45 ▲

Step 1

Pre-operatively, the surgeon must identify the proper intervertebral level to fuse using diagnostic techniques such as radiography, 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. (Fig. 45)

Exposure and Location, and Site Preparation

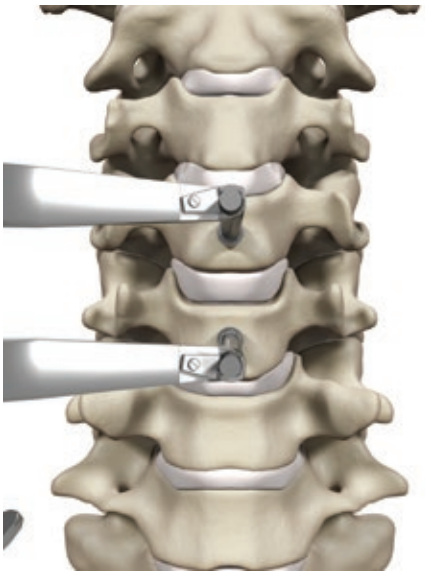


Fig. 46 ▲

Step 2

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. (Fig. 46)

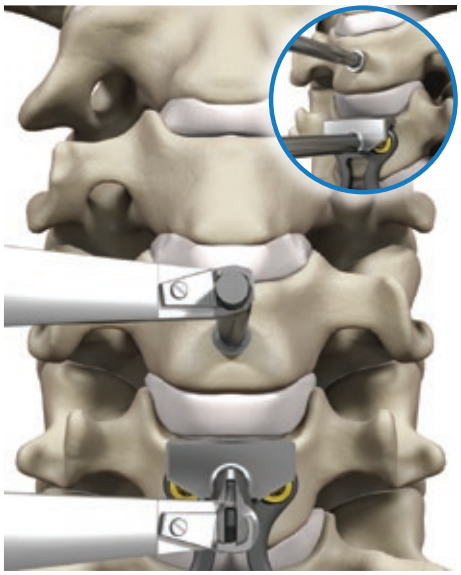


Fig. 47 ▲

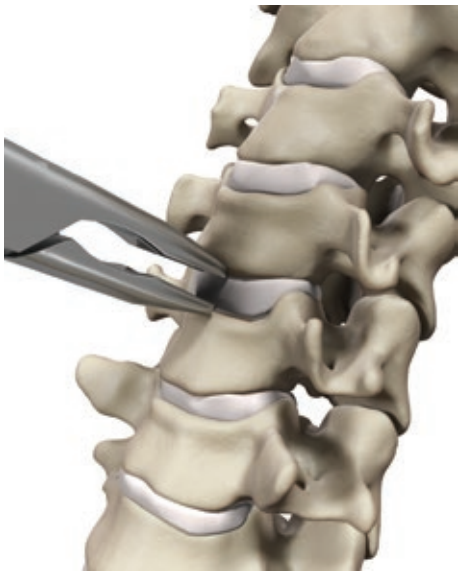


Fig. 48 ▲

Plate Sizing

Fig. 49 ▲

Step 3

For placement adjacent to existing plate hardware, the Optio-C Distraction Pin Instruments can be used with a Caspar Distractor over the existing plate hardware in lieu of a Caspar Pin in that vertebral segment. (Fig. 47)

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.*

Step 4

Prepare the anatomy to accommodate placement of the structural allograft/autograft and the Optio-C plate. It is recommended to insert the Optio-C plate under distraction. (Fig. 48)

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.*

Step 5

The Optio-C Plate is designed to be used with one structural allograft/autograft of the same height as the plate. Determine trial size for assessing the disc space. Connect the Modular Impaction Cap Handle to the appropriately sized height trial. Select the plate height by using the trial to assess the anterior height of the disc space. The Optio-C plate must be implanted with a structural allograft/autograft. The plate height should match the anterior height of the disc space. If the disc space is 7 mm, the 7 mm height Optio-C plate should be selected. (Fig. 49)

NOTE: *The Optio-C plate height is measured from the tips of the splines. All Optio-C plates are 16mm wide.*

NOTE: *Prepare the disc space to accommodate placement of the Optio-C plate between adjacent vertebrae.*

NOTE: *Intraoperative imaging can be used with the system trials to approximate implant sizing.*

Instruments

Distraction Pins
07.01911.001
Single Prong
07.01911.002
Double Prong

Modular Handle—
Impaction Cap
07.01903.001

Implant Trials—
Parallel and Lordotic
07.01877.006 – 012, .026, .046
07.01879.006 – 012

Implant Rasps—
Parallel and Lordotic
07.01878.006 – 012, .026, .046
07.01880.006 – 012

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

Allograft/Autograft Selection

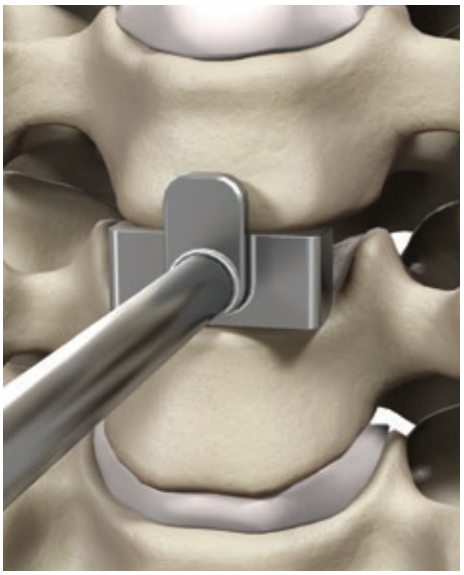


Fig. 50 ▲

Step 6

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. The Optio-C plate must be implanted with a structural allograft/autograft.

Once the height is determined, select the appropriate plate footprint by using the Trials and Rasps (12 × 14, 14 × 16, or 15 × 18). These instruments equal the shape of the plate plus structural allograft/autograft. (Fig. 50)

Allograft/Autograft Placement

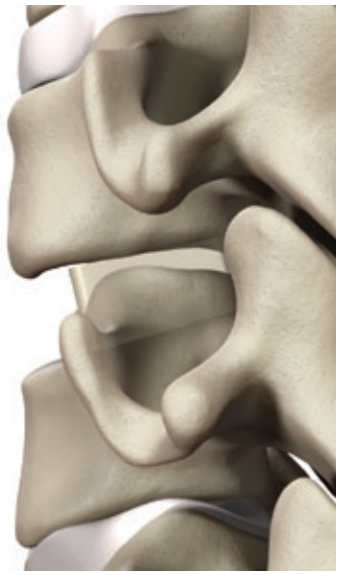


Fig. 51 ▲

Step 7

If a structural allograft/autograft is used, select a graft size that:

- Has the same height of the Optio-C plate,
- Fits within the lateral walls of the Optio-C plate and,
- Accommodates the plate thickness of 4 mm.

Refer to the chart below to select the recommended structural allograft/autograft per the Trial chosen.

Trial (L × W)	Recommended Graft Size (L × W)
12 × 14 mm	8 × 11 mm
14 × 16 mm	10 × 11 mm
15 × 18 mm	11 × 11 mm

If using allograft, prepare the allograft per the manufacturer's instructions. Countersink the graft at least 4mm from the anterior margin of the vertebral body upon final placement. The system Rasps can

be used to help prepare the endplates. (Fig.51)

Attaching the Plate

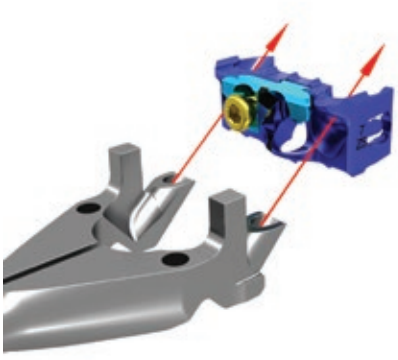


Fig. 52 ▲

Step 8

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. (Fig. 52)

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).*

Instruments

Modular Handle—
Impaction Cap
07.01903.001

Inserter Guide
07.01886.001

Plate Placement

Fig. 53 ▲

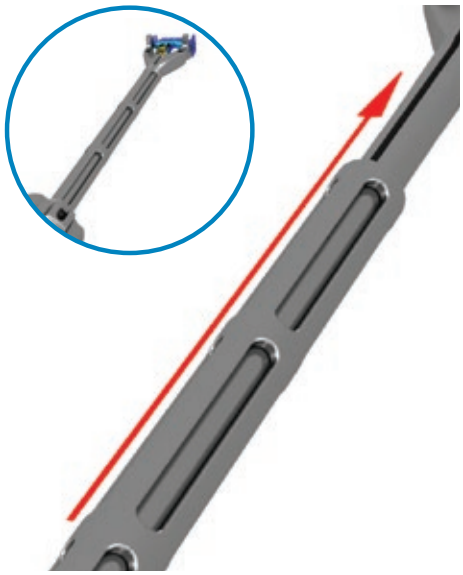


Fig. 54 ▲

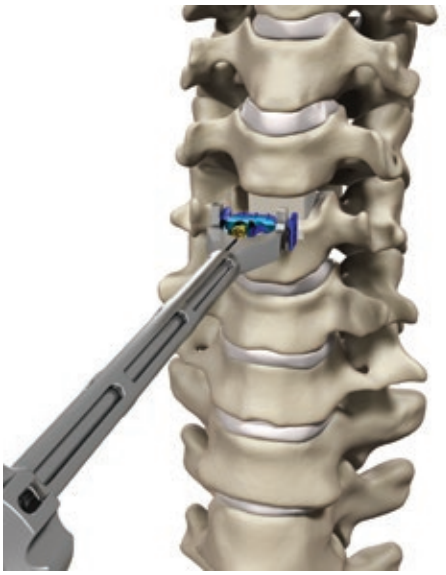


Fig. 55 ▲

Step 9

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 that the guide holes and lateral plate holes are aligned, and that the inserter axis is perpendicular to the anterior face of the plate. (Fig. 53)

Step 10

Secure the plate 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 threads until secure. (Fig. 54)

Step 11

Once the plate is attached securely to the inserter, insert the plate into the distracted segment. If necessary, use light impaction to advance the plate into the disc space. (Fig. 55)

NOTE: *Positive stops position the plate flush with the anterior aspect of the vertebral bodies.*

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

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

Lateral Screw Hole Preparation / Screw Placement

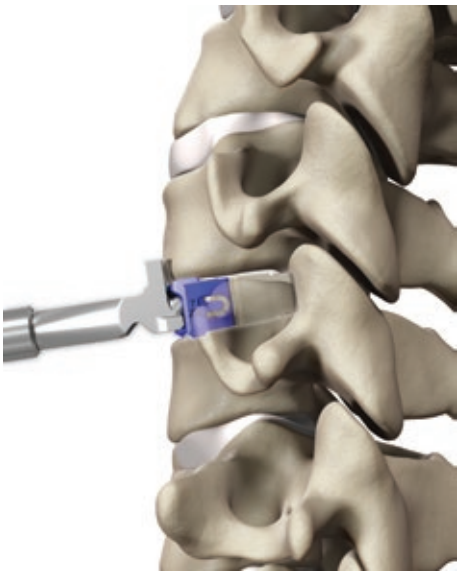


Fig. 56 ▲

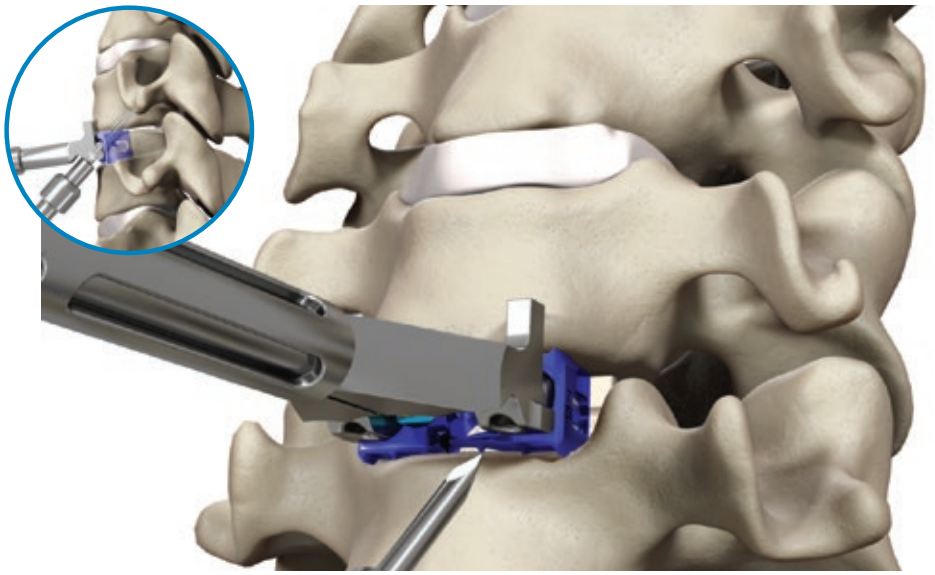


Fig. 57 ▲

Step 12

Ensure that the plate and structural allograft/autograft fit snugly between the adjacent vertebrae, and then release distraction while leaving the Inserter Guide attached to the plate. The Modular Handle may be temporarily removed from the inserter to increase visibility for screw preparation and delivery. (Fig. 56)

NOTE: *If using the Distraction Pin, remove the Distraction Pin with the Caspar Distractor.*

Step 13

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 and/or Drill (Straight, Flexible or U-Joint options) to pass through its guide holes to prepare the two lateral screw holes while the Inserter Guide is secured to the plate.

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 plate. (Fig. 57)

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

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. Before 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.*

Instruments

Modular Handle—Spin Cap
07.01902.001

Awls
07.01894.001 Straight
07.01897.001 Flexible
07.01890.001 U-Joint

Drills
07.01893.001 Straight
07.01896.001 Flexible
07.01891.001 U-Joint

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

Midline Screw Hole Preparation / Screw Placement

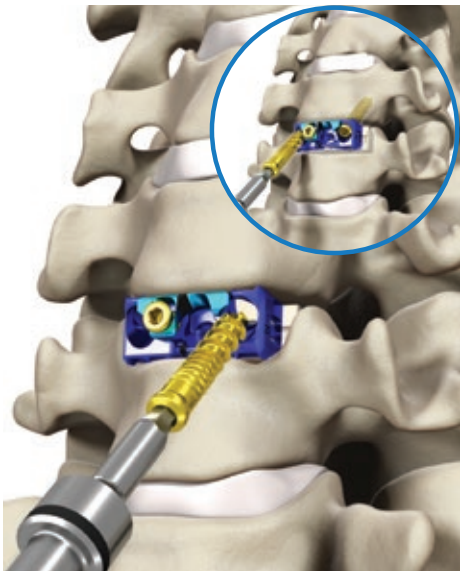


Fig. 58 ▲

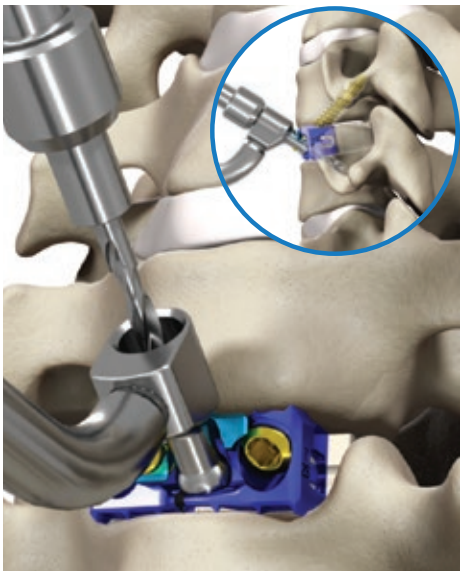


Fig. 59 ▲

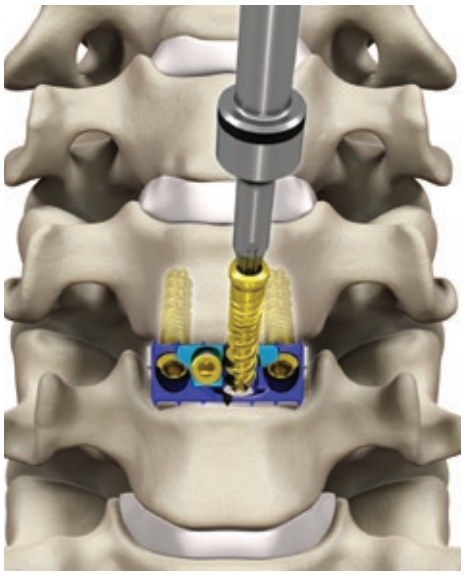


Fig. 60 ▲

Step 14

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 provisionally stabilize the plate. Ensure that the Driver is on axis to the prepared screw trajectory during screw insertion. Repeat on the contralateral side. (Fig. 58)

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

Step 15

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 to determine the appropriate screw length. (Fig. 59)

Step 16

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 the Driver is on axis to the prepared screw trajectory during screw insertion and final tightening. (Fig. 60)

Instruments

Modular Handle—
Spin Cap
07.01902.001

2.0 mm Hex Drivers
07.01895.001
Straight
07.01898.001
Flexible
07.01910.001
U-Joint

Guides
07.01888.001
Fixed Angle (gold end)
07.01889.001
Variable Angle
(silver end)

Awls
07.01894.001
Straight
07.01897.001
Flexible
07.01890.001
U-Joint

Drills
07.01893.001
Straight
07.01896.001
Flexible
07.01891.001
U-Joint

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

Final Tightening of Bone Screws

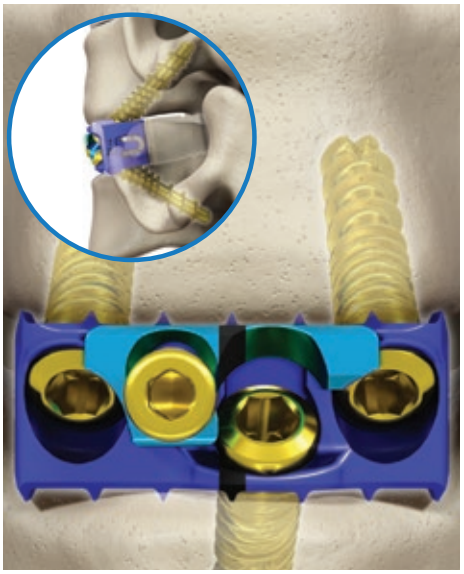


Fig. 61 ▲

Step 17

Completely engage the 2.0 mm Hex Driver in each screw head and fully seat all bone screws. (Fig. 61)

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 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

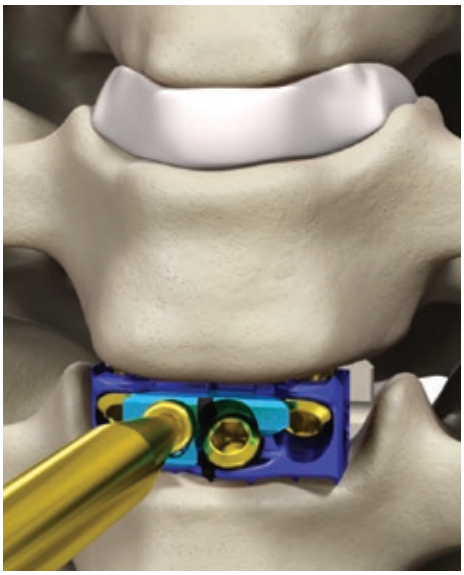


Fig. 62 ▲

Step 18

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. (Fig. 62)

Fig. 63 ▲

Step 19

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. (Fig. 63)

Instruments

Torque Limiting Handle
07.01901.001

Locking Cap Driver
07.01900.001

Surgical Technique

Option 2: Structural Allograft/ Autograft of the Same Height as the Optio-C Plate

ATO Inserter Guide (Optional)

Description

The Optio-C Plate can also be used with an Optio-C Allograft or a structural allograft/autograft of the same height as the Optio-C Plate. The structural allograft/autograft width selection is specifically chosen to fit within the lateral walls of the Optio-C plate. The decision whether to use an Optio-C Allograft or a structural allograft/autograft is based on surgeon preference; both options are appropriate for use with the stated indications.

The surgeon must exercise his/her best judgment to prevent interference with the Optio-C plate and screws based on the position of the structural allograft/autograft, which is also in the intervertebral space.

Planning, Positioning and Exposure

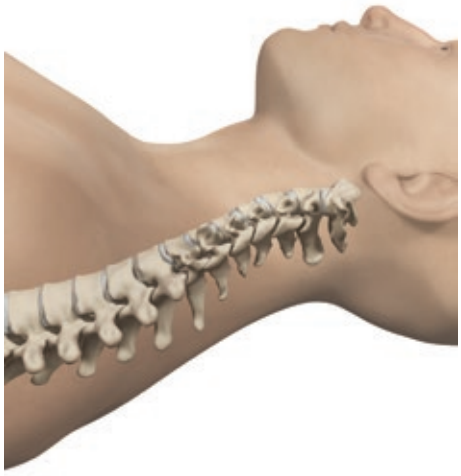


Fig. 64 ▲

Step 1

Repeat step 1, Pre-operative Planning, through step 7, of Option 2, pages 23–25. (Fig. 64)

Attaching the Plate

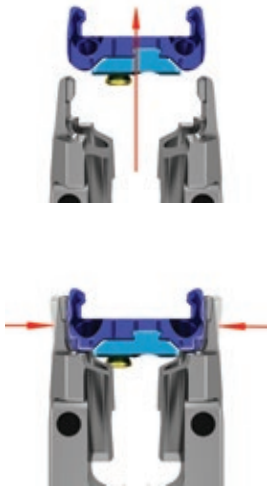


Fig. 65 ▲

Step 2

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. (Fig. 65, 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.* (Fig. 65, bottom)

Instruments

Modular Handle—
Impaction Cap
07.01903.001

ATO Inserter Guide
07.01887.001
Optional instrument. Available upon request.

Plate Placement

Fig. 66 ▲

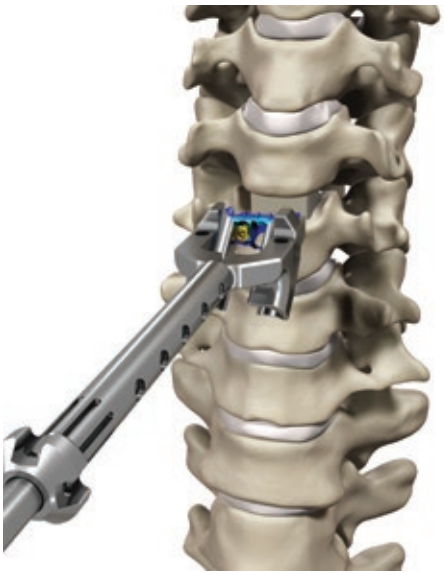


Fig. 67 ▲

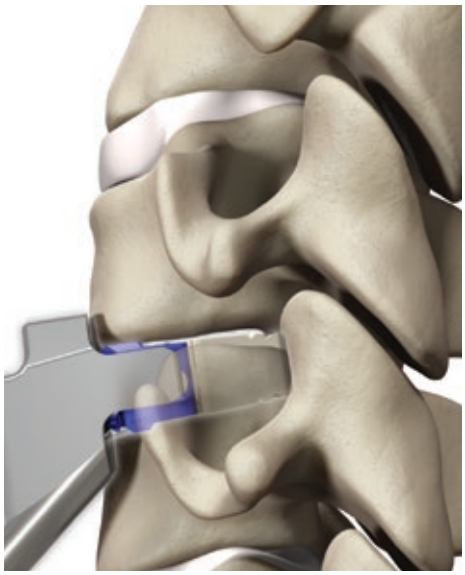


Fig. 68 ▲

Step 3

Ensure that the inserter is fully seated on the plate 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. (Fig. 66)

Secure the plate by sliding the ATO Inserter Guide sleeve toward the plate until it bottoms out on the distal end of the ATO Inserter Guide. (Fig. 66, inset)

Step 4

Insert the plate into the distracted segment. If necessary, use light impaction to advance the plate into the disc space. (Fig. 67)

NOTE: *Positive stops position the plate and structural allograft/autograft flush with the anterior aspect of the vertebral bodies.*

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

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

Step 5

Ensure that the plate 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 removed temporarily from the inserter to increase visibility for screw preparation and delivery. (Fig. 68)

NOTE: *If using the Distraction Pin, remove the Distraction Pin with the Caspar Distractor.*

Lateral Screw Hole Preparation/ Screw Placement

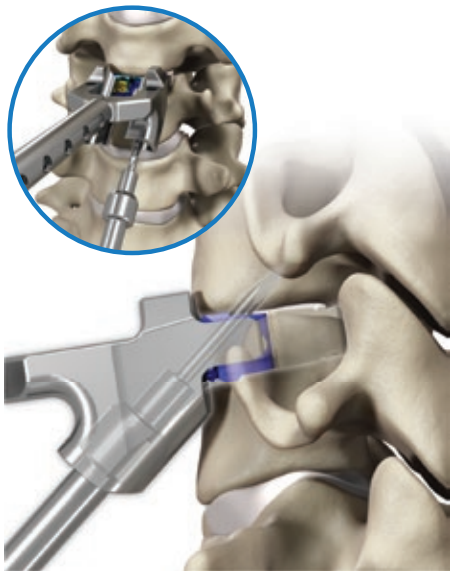


Fig. 69 ▲

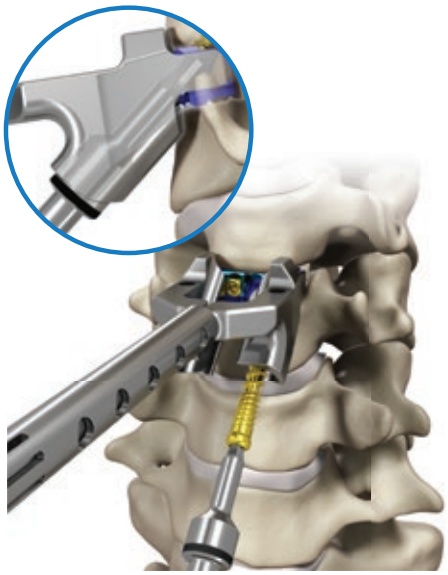


Fig. 70 ▲

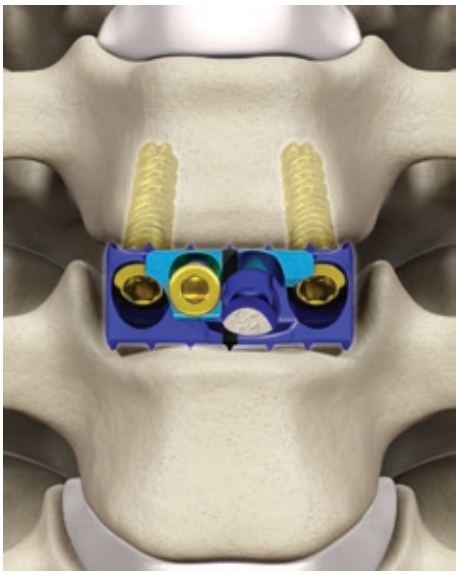


Fig. 71 ▲

Step 6

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 plate. 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 determine the appropriate length screw. Remove the Awl/Drill. Repeat the same steps on the contralateral side. (Fig. 69)

Step 7

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 provisionally stabilize the plate. Ensure that the Driver is on axis to the prepared screw trajectory during screw insertion and final tightening. (Fig. 70)

The Driver laser marking approaches the edge of the guide tube to indicate that the screw is nearly seated. (Fig. 70, inset)

Step 8

Repeat step 7 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 plate using a gentle side-to-side motion. (Fig. 71)

NOTE: *If self-drilling screws are used, the awl/drilling 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.*

Instruments

Modular Handle—
Spin Cap
07.01902.001

Awls
07.01894.001 Straight
07.01897.001 Flexible

Drills
07.01893.001 Straight
07.01896.001 Flexible

2.0 mm Hex Drivers
07.01895.001 Straight
07.01898.001 Flexible

Midline Screw Hole Preparation/ Screw Placement

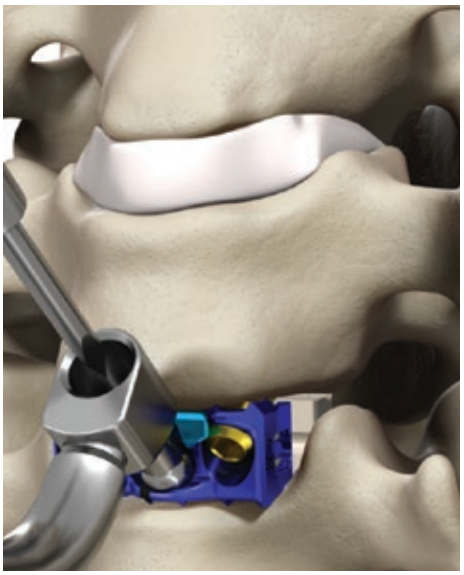


Fig. 72 ▲

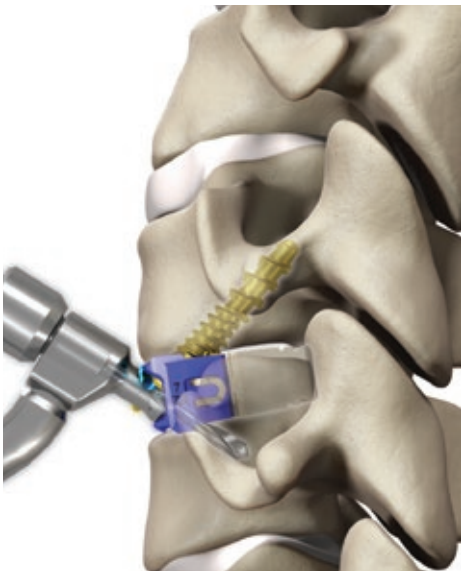


Fig. 73 ▲

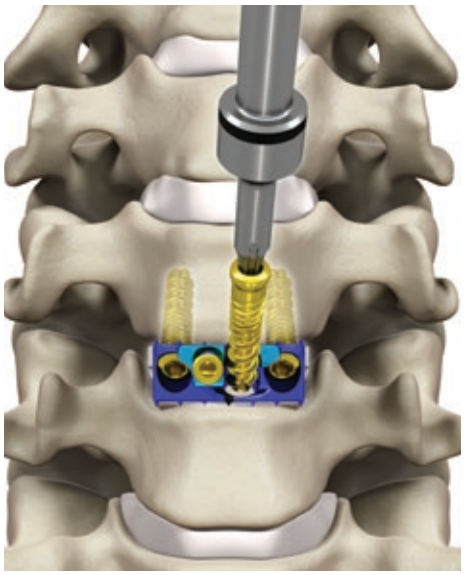


Fig. 74 ▲

Step 9

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. (Fig. 72)

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 6mm deep. Intra-operative imaging should be used to verify Awl/Drill position and determine the appropriate screw length. (Fig. 73)

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. Before 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.*

Step 10

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 plate. Ensure that the Driver is on axis to the prepared screw trajectory during screw insertion and final tightening. (Fig. 74)

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

Instruments

Guides
07.01888.001
Fixed Angle (gold end)
07.01889.001
Variable Angle (silver end)

Modular Handle—
Spin Cap
07.01902.001

Awls
07.01894.001
Straight
07.01897.001
Flexible
07.01890.001
U-Joint

Drills
07.01893.001
Straight
07.01896.001
Flexible
07.01891.001
U-Joint

2.0 mm Hex Drivers
07.01895.001
Straight
07.01898.001
Flexible
07.01910.001
U-Joint

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

Final Tightening of Bone Screws

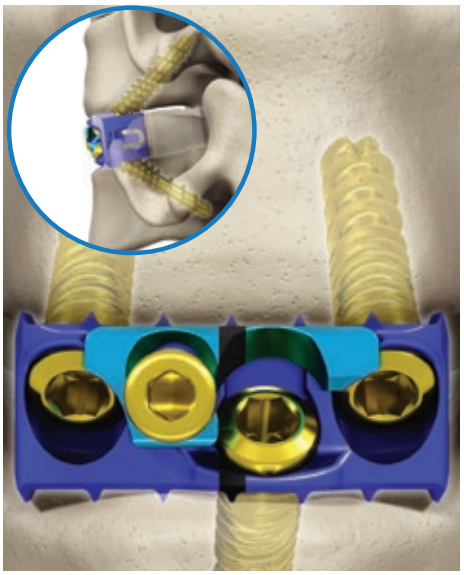


Fig. 75 ▲

Step 11

Completely engage the 2.0 mm Hex Driver in each screw head and fully seat all bone screws. (Fig. 75)

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

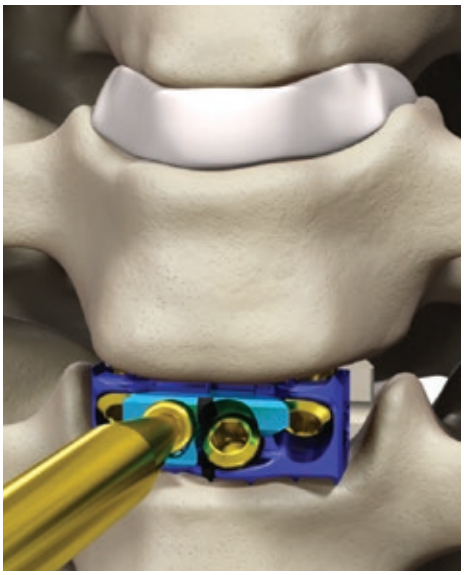


Fig. 76 ▲

Step 12

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. (Fig. 76)

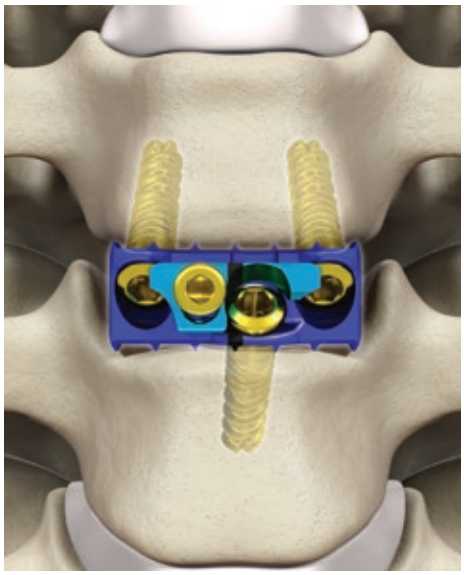


Fig. 77 ▲

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 4in-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. (Fig. 77)

Instruments

Torque Limiting Handle
07.01901.001

Locking Cap Driver
07.01900.001

Surgical Technique

Option 2: Structural Allograft/ Autograft of the Same Height as the Optio-C Plate

Freehand Screw Insertion

Description

The Optio-C Plate can also be used with an Optio-C Allograft or a structural allograft/autograft of the same height as the Optio-C Plate. The structural allograft/autograft width selection is chosen specifically to fit within the lateral walls of the Optio-C plate. The decision whether to use an Optio-C Allograft or a structural allograft/autograft is based on surgeon preference; both options are appropriate for use with the stated indications.

The surgeon must exercise his/her best judgment to prevent interference with the Optio-C plate and screws based on the position of the structural allograft/autograft, which is also in the intervertebral space.

Planning, Positioning and Exposure

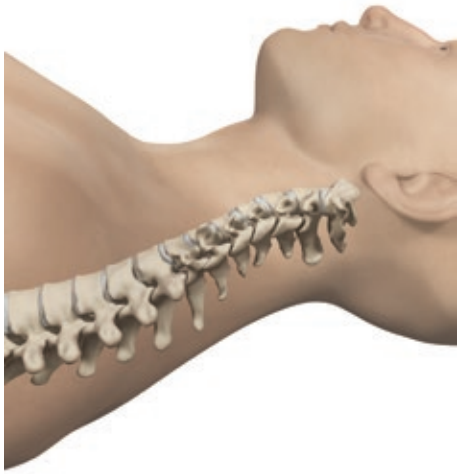


Fig. 78 ▲

Step 1

Repeat step 1, Pre-operative Planning, through step 7, of Option 2, pages 23–25. (Fig. 78)

Plate Insertion

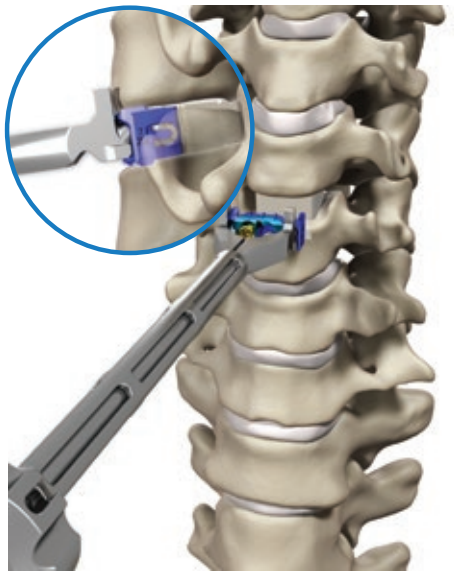


Fig. 79 ▲

Step 2

Once the plate is attached securely to the inserter, insert the plate into the distracted segment. If necessary, use light impaction to advance the plate into the disc space. (Fig. 79)

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

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

Instruments

Modular Handle—
Impaction Cap
07.01903.001

Inserter Guide
07.01886.001

Screw Hole Preparation/Screw

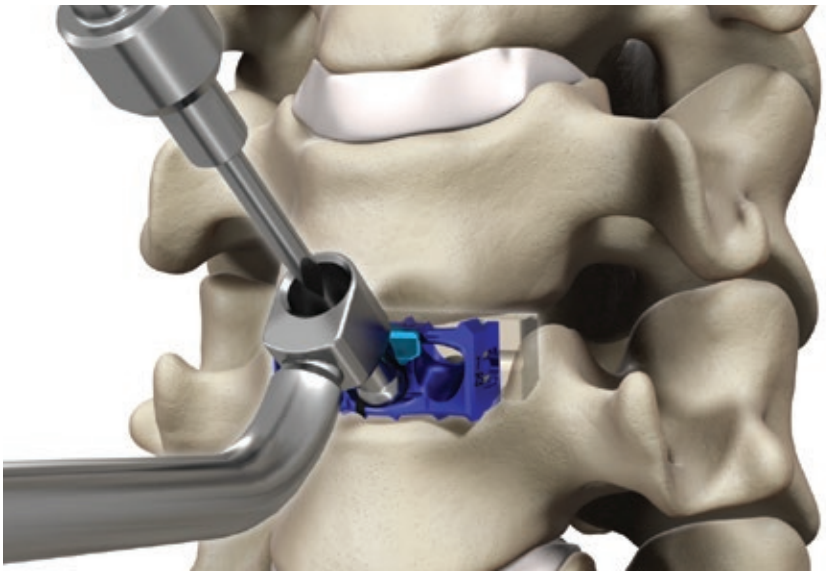


Fig. 80 ▲

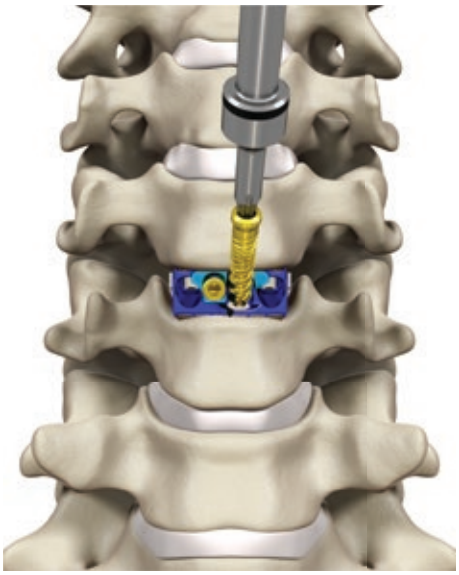


Fig. 81 ▲

Step 3

Remove the inserter from the plate. 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 to determine the appropriate length screw. (Fig. 80)

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 only be made under slight distraction. Care should be taken when using the Tamp because it does not have a positive stop.*

Step 4

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 plate and structural allograft/autograft of the same height. (Fig. 81)

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.*

Instruments

Modular Handle—
Spin Cap
07.01902.001

Awls
07.01894.001
Straight
07.01897.001
Flexible
07.01890.001
U-Joint

Drills
07.01893.001
Straight
07.01896.001
Flexible
07.01891.001
U-Joint

Guides
07.01888.001
Fixed Angle (gold end)
07.01889.001
Variable Angle
(silver end)

2.0 mm Hex Drivers
07.01895.001
Straight
07.01898.001
Flexible
07.01910.001
U-Joint

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

Tamp (optional)
07.01899.001

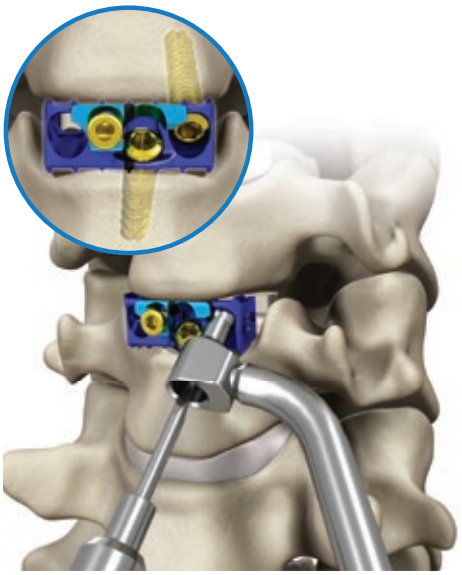


Fig. 82 ▲

Step 5

Repeat steps 3 and 4 for the lateral screws, using the same "drill and fill" technique. (Fig. 82)

NOTE: *Use care to maintain the plate and structural allograft/autograft.*

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

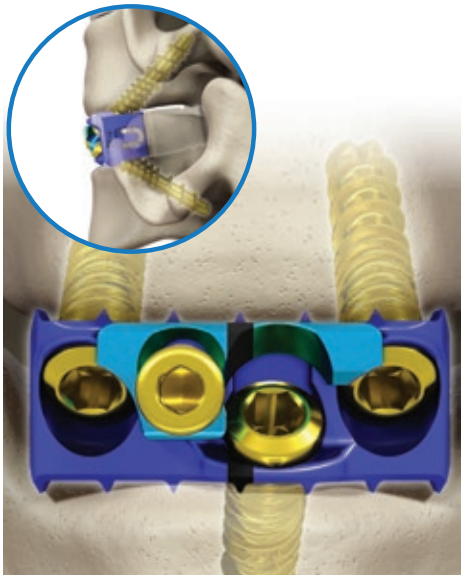


Fig. 83 ▲

Step 6

Completely engage the 2.0 mm Hex Driver in each screw head and fully seat all bone screws. (Fig. 83)

NOTE: *Failure to seat the screws fully 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

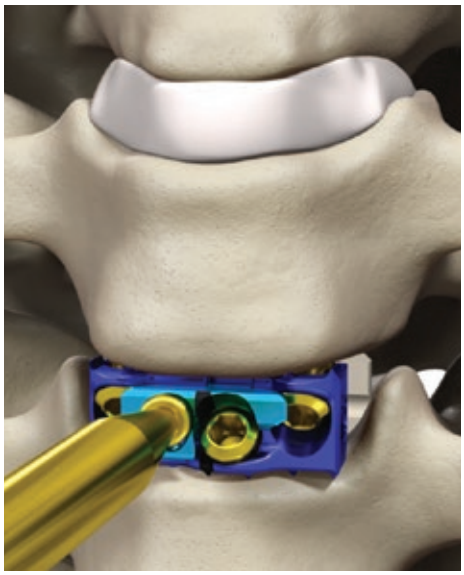


Fig. 84 ▲

Step 7

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. (Fig. 84)

Instruments

Torque Limiting Handle
07.01901.001

Locking Cap Driver
07.01900.001

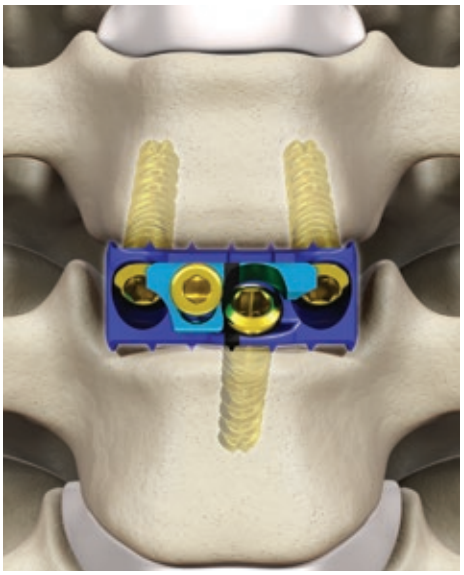


Fig. 85 ▲

Step 7 *(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. (Fig. 85)

Removal/ Revision

Surgical Technique

Plate and Structural Allograft/ Autograft Removal

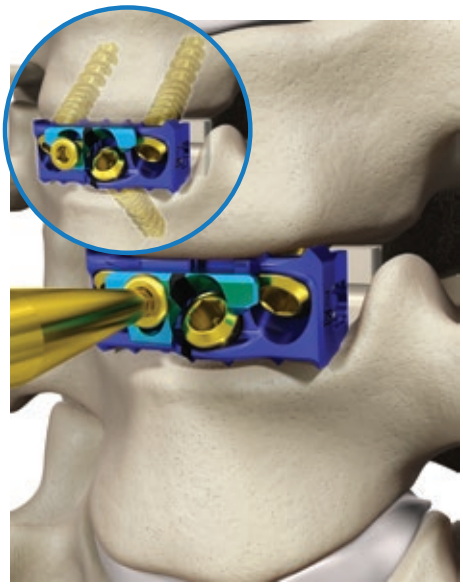


Fig. 86 ▲

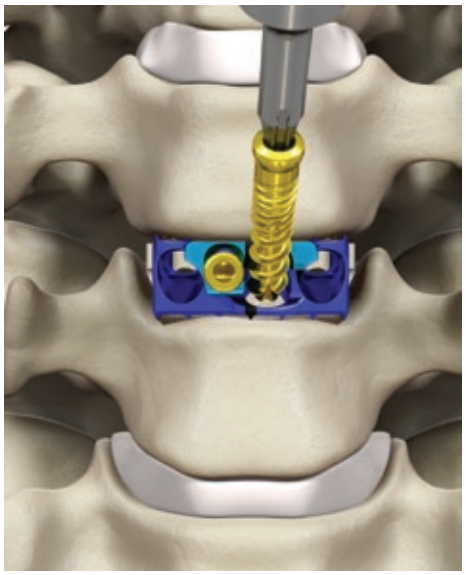


Fig. 87 ▲

Step 1

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 plate 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. (Fig. 86)

Step 2

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 plate through the surgical opening. Next, remove the structural allograft/autograft through the surgical opening. (Fig. 87)

WARNING: *Do not reuse a plate after removal.*

Instruments

Locking Cap Driver
07.01900.001

Torque Limiting Handle
07.01901.001

2.0 mm Hex Drivers
07.01895.001
Straight
07.01898.001
Flexible
07.01910.001
U-Joint

Modular Handle—
Spin Cap
07.01902.001

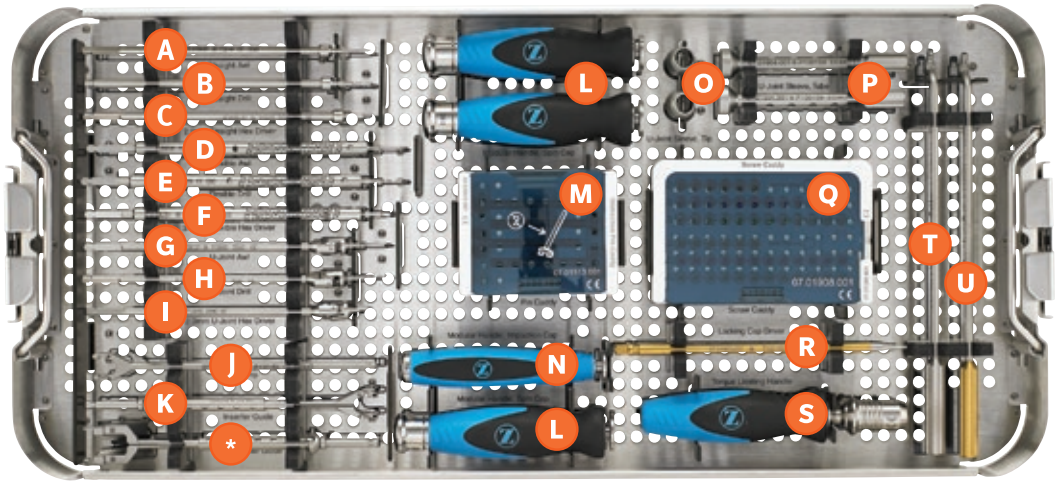
Inserter Guide
07.01886.001

Modular Handle—
Impaction Cap
07.01903.001

Tray Layouts

Optio-C System Core Instrument Set

07.01974.402

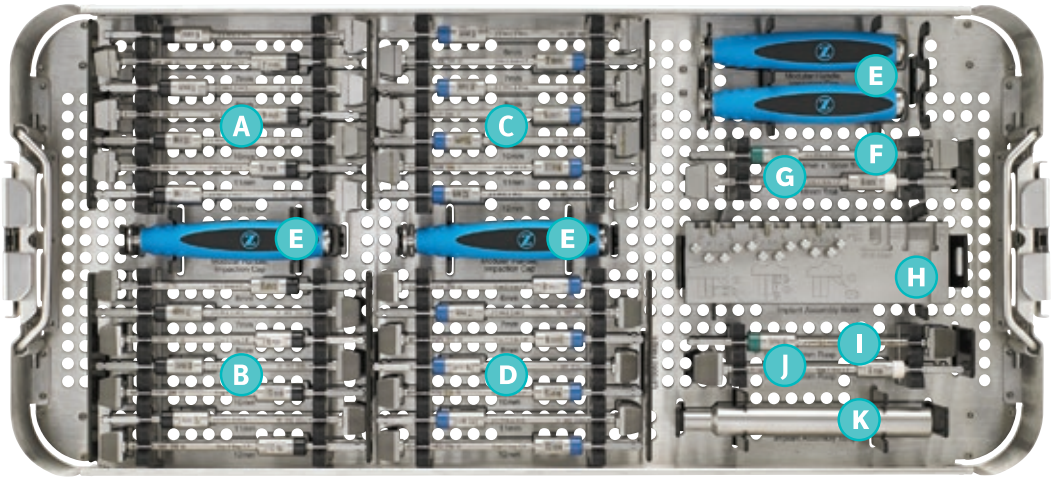


Part Number	Description	Quantity	Reference
07.01260.001	Generic Lid	1	-
07.01874.012	Optio-C Screw, 12 mm, Variable, Self-tapping	12	(Q)
07.01874.014	Optio-C Screw, 14 mm, Variable, Self-tapping	12	(Q)
07.01874.016	Optio-C Screw, 16 mm, Variable, Self-tapping	6	(Q)
07.01875.012	Optio-C Screw, 12 mm, Variable, Self-drilling	12	(Q)
07.01875.014	Optio-C Screw, 14 mm, Variable, Self-drilling	12	(Q)
07.01875.016	Optio-C Screw, 16 mm, Variable, Self-drilling	6	(Q)
07.01886.001	Inserter Guide	1	K
07.01888.001	Fixed Angle Guide	1	U
07.01889.001	Variable Angle Guide	1	T
07.01890.001	U-Joint Awl	1	G
07.01891.001	U-Joint Drill	1	H
07.01893.001	Straight Drill	2	B
07.01894.001	Straight Awl	1	A
07.01895.001	2.0 mm Straight Hex Driver	2	C
07.01896.001	Flexible Drill	1	E
07.01897.001	Flexible Awl	1	D
07.01898.001	2.0 mm Flexible Hex Driver	1	F
07.01899.001	Tamp	1	J
07.01900.001	Locking Cap Driver	2	R
07.01901.001	Torque Limiting Handle	1	S
07.01902.001	Modular Handle, Spin Cap	3	L
07.01903.001	Modular Handle, Impaction Cap	1	N
07.01904.001	U-Joint Sleeve, Tube	2	P
07.01905.001	U-Joint Sleeve, Tip	2	O
07.01907.001	Core Tray	1	-
07.01908.001	Screw Caddy Lid	1	-
07.01909.001	Screw Caddy	1	Q
07.01910.001	2.0 mm U-Joint Hex Driver	1	I
07.01911.001	Distraction Pin, Single Prong	2	(M)
07.01911.002	Distraction Pin, Double Prong	2	(M)
07.01912.001	Distraction Pin Caddy	1	M
07.01913.001	Distraction Pin Caddy Lid	1	-
07.01964.001	Optio-C System Non-Sterile Implant and Instrument IFU	1	-

* 07.01887.001 ATO Inserter Guide. This instrument is optional and must be ordered separately. Tray location is for the ATO Inserter Guide placement, which meets validated sterilization parameters.

Optio-C System Bone Prep Instrument Set

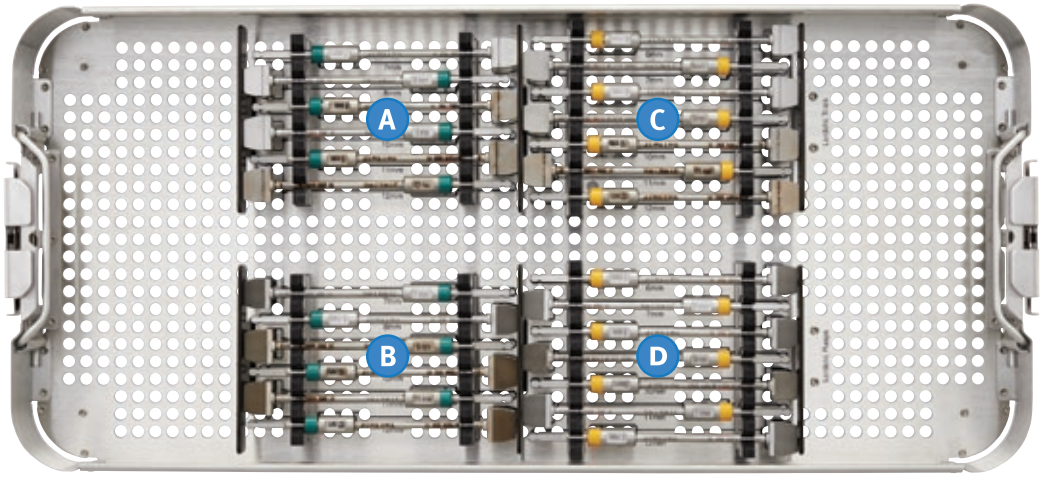
07.01974.401



Part Number	Description	Quantity	Reference
07.01260.001	Generic Lid	1	-
07.01877.006	Parallel Trial, 12 × 14 × 6 mm	1	A
07.01877.007	Parallel Trial, 12 × 14 × 7 mm	1	A
07.01877.008	Parallel Trial, 12 × 14 × 8 mm	1	A
07.01877.009	Parallel Trial, 12 × 14 × 9 mm	1	A
07.01877.010	Parallel Trial, 12 × 14 × 10 mm	1	A
07.01877.011	Parallel Trial, 12 × 14 × 11 mm	1	A
07.01877.012	Parallel Trial, 12 × 14 × 12 mm	1	A
07.01877.026	Parallel Trial, 14 × 16 × 6 mm	1	F
07.01877.046	Parallel Trial, 15 × 18 × 6 mm	1	G
07.01878.006	Parallel Rasp, 12 × 14 × 6 mm	1	B
07.01878.007	Parallel Rasp, 12 × 14 × 7 mm	1	B
07.01878.008	Parallel Rasp, 12 × 14 × 8 mm	1	B
07.01878.009	Parallel Rasp, 12 × 14 × 9 mm	1	B
07.01878.010	Parallel Rasp, 12 × 14 × 10 mm	1	B
07.01878.011	Parallel Rasp, 12 × 14 × 11 mm	1	B
07.01878.012	Parallel Rasp, 12 × 14 × 12 mm	1	B
07.01878.026	Parallel Rasp, 14 × 16 × 6 mm	1	I
07.01878.046	Parallel Rasp, 15 × 18 × 6 mm	1	J
07.01879.006	Lordotic Trial, 12 × 14 × 6 mm	1	C
07.01879.007	Lordotic Trial, 12 × 14 × 7 mm	1	C
07.01879.008	Lordotic Trial, 12 × 14 × 8 mm	1	C
07.01879.009	Lordotic Trial, 12 × 14 × 9 mm	1	C
07.01879.010	Lordotic Trial, 12 × 14 × 10 mm	1	C
07.01879.011	Lordotic Trial, 12 × 14 × 11 mm	1	C
07.01879.012	Lordotic Trial, 12 × 14 × 12 mm	1	C
07.01880.006	Lordotic Rasp, 12 × 14 × 6 mm	1	D
07.01880.007	Lordotic Rasp, 12 × 14 × 7 mm	1	D
07.01880.008	Lordotic Rasp, 12 × 14 × 8 mm	1	D
07.01880.009	Lordotic Rasp, 12 × 14 × 9 mm	1	D
07.01880.010	Lordotic Rasp, 12 × 14 × 10 mm	1	D
07.01880.011	Lordotic Rasp, 12 × 14 × 11 mm	1	D
07.01880.012	Lordotic Rasp, 12 × 14 × 12 mm	1	D
07.01884.001	Implant Assembly Block	1	H
07.01885.001	Implant Assembly Tamp	1	K
07.01903.001	Modular Handle, Impaction Cap	4	E
07.01906.001	Bone Prep Tray	1	-
07.01964.001	Optio-C System Non-Sterile Implant and Instrument IFU	1	-

Optio-C System 14 × 16 Auxiliary Instruments

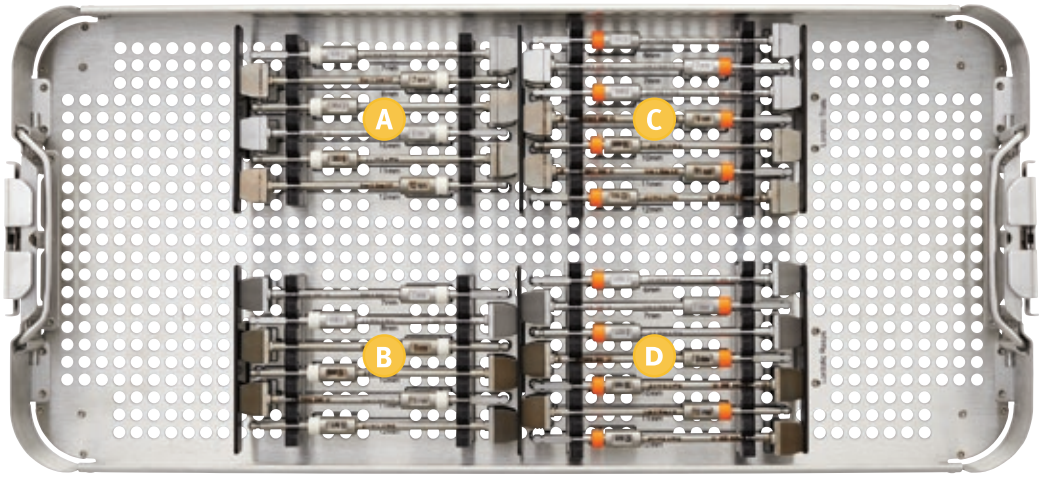
07.01975.401



Part Number	Description	Quantity	Reference
07.01260.001	Generic Lid	1	-
07.01877.027	Parallel Trial, 14 × 16 × 7 mm	1	A
07.01877.028	Parallel Trial, 14 × 16 × 8 mm	1	A
07.01877.029	Parallel Trial, 14 × 16 × 9 mm	1	A
07.01877.030	Parallel Trial, 14 × 16 × 10 mm	1	A
07.01877.031	Parallel Trial, 14 × 16 × 11 mm	1	A
07.01877.032	Parallel Trial, 14 × 16 × 12 mm	1	A
07.01878.027	Parallel Rasp, 14 × 16 × 7 mm	1	B
07.01878.028	Parallel Rasp, 14 × 16 × 8 mm	1	B
07.01878.029	Parallel Rasp, 14 × 16 × 9 mm	1	B
07.01878.030	Parallel Rasp, 14 × 16 × 10 mm	1	B
07.01878.031	Parallel Rasp, 14 × 16 × 11 mm	1	B
07.01878.032	Parallel Rasp, 14 × 16 × 12 mm	1	B
07.01879.026	Lordotic Trial, 14 × 16 × 6 mm	1	C
07.01879.027	Lordotic Trial, 14 × 16 × 7 mm	1	C
07.01879.028	Lordotic Trial, 14 × 16 × 8 mm	1	C
07.01879.029	Lordotic Trial, 14 × 16 × 9 mm	1	C
07.01879.030	Lordotic Trial, 14 × 16 × 10 mm	1	C
07.01879.031	Lordotic Trial, 14 × 16 × 11 mm	1	C
07.01879.032	Lordotic Trial, 14 × 16 × 12 mm	1	C
07.01880.026	Lordotic Rasp, 14 × 16 × 6 mm	1	D
07.01880.027	Lordotic Rasp, 14 × 16 × 7 mm	1	D
07.01880.028	Lordotic Rasp, 14 × 16 × 8 mm	1	D
07.01880.029	Lordotic Rasp, 14 × 16 × 9 mm	1	D
07.01880.030	Lordotic Rasp, 14 × 16 × 10 mm	1	D
07.01880.031	Lordotic Rasp, 14 × 16 × 11 mm	1	D
07.01880.032	Lordotic Rasp, 14 × 16 × 12 mm	1	D
07.01914.001	Auxiliary 14 × 16 Tray	1	-
07.01964.001	Optio-C System Non-Sterile Implant and Instrument IFU	1	-

Optio-C System 15 × 18 Auxiliary Instruments

07.01976.401



Part Number	Description	Quantity	Reference
07.01260.001	Generic Lid	1	-
07.01877.047	Parallel Trial, 15 × 18 × 7 mm	1	A
07.01877.048	Parallel Trial, 15 × 18 × 8 mm	1	A
07.01877.049	Parallel Trial, 15 × 18 × 9 mm	1	A
07.01877.050	Parallel Trial, 15 × 18 × 10 mm	1	A
07.01877.051	Parallel Trial, 15 × 18 × 11 mm	1	A
07.01877.052	Parallel Trial, 15 × 18 × 12 mm	1	A
07.01878.047	Parallel Rasp, 15 × 18 × 7 mm	1	B
07.01878.048	Parallel Rasp, 15 × 18 × 8 mm	1	B
07.01878.049	Parallel Rasp, 15 × 18 × 9 mm	1	B
07.01878.050	Parallel Rasp, 15 × 18 × 10 mm	1	B
07.01878.051	Parallel Rasp, 15 × 18 × 11 mm	1	B
07.01878.052	Parallel Rasp, 15 × 18 × 12 mm	1	B
07.01879.046	Lordotic Trial, 15 × 18 × 6 mm	1	C
07.01879.047	Lordotic Trial, 15 × 18 × 7 mm	1	C
07.01879.048	Lordotic Trial, 15 × 18 × 8 mm	1	C
07.01879.049	Lordotic Trial, 15 × 18 × 9 mm	1	C
07.01879.050	Lordotic Trial, 15 × 18 × 10 mm	1	C
07.01879.051	Lordotic Trial, 15 × 18 × 11 mm	1	C
07.01879.052	Lordotic Trial, 15 × 18 × 12 mm	1	C
07.01880.046	Lordotic Rasp, 15 × 18 × 6 mm	1	D
07.01880.047	Lordotic Rasp, 15 × 18 × 7 mm	1	D
07.01880.048	Lordotic Rasp, 15 × 18 × 8 mm	1	D
07.01880.049	Lordotic Rasp, 15 × 18 × 9 mm	1	D
07.01880.050	Lordotic Rasp, 15 × 18 × 10 mm	1	D
07.01880.051	Lordotic Rasp, 15 × 18 × 11 mm	1	D
07.01880.052	Lordotic Rasp, 15 × 18 × 12 mm	1	D
07.01915.001	Auxialiary 15 × 18 Tray	1	-
07.01964.001	Optio-C System Non-Sterile Implant and Instrument IFU	1	-

Visual Instrument Guide

Torque Limiting Handle
07.01901.001

Modular Handle—Spin Cap
07.01902.001

Modular Handle—Impaction Cap
07.01903.001

Distraction Pins
07.01911.001 Single Prong
07.01911.002 Double Prong

Implant Trials—Parallel and Lordotic
Parallel Trial 12 × 14, 6–12 mm (1mm 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 (1mm increments)
07.01879.006–07.01879.012

Implant Rasps—Parallel and Lordotic
Parallel Rasp 12 × 14, 6–12 mm (1mm 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 (1mm increments)
07.01880.006 – 07.01880.012

Inserter Guide
07.01886.001

ATO Inserter Guide* (optional)
07.01887.001

Fixed Angle Guide
07.01888.001

Variable Angle Guide
07.01889.001

Tamp
07.01899.001

Locking Cap Driver
07.01900.001

* Must be ordered separately.

U-Joint Instruments
U-Joint Awl
07.01890.001

U-Joint Drill
07.01891.001

U-Joint 2.0 mm Hex Driver
07.01910.001

U-Joint Sleeve Tube
07.01904.001

U-Joint Sleeve Tip
07.01905.001

Straight Instruments
Straight Awl
07.01894.001

Straight Drill
07.01893.001

Straight 2.0 mm Hex Driver

Flexible Instruments
Flexible Awl
07.01897.001

Flexible Drill
07.01896.001

Flexible 2.0 mm Hex Driver
07.01898.001

Implant Assembly Block
07.01884.001

Implant Assembly Tamp
07.01885.001

Important Information on the Optio-C Anterior Cervical Plate with Allograft/Autograft

DESCRIPTION

The Optio-C Plate is a component of the Optio-C Anterior Cervical System and is intended to be used only in anterior surgical procedures. The Optio-C Plate must be used with three Optio-C bone screws it is designed to be used with either one of the following:

- One Optio-C structural allograft or
- One structural allograft/autograft of the same height

The Optio-C Anterior Cervical System is secured by an anti-migration locking system that is designed to maintain no profile. The Optio-C System is designed to maximize fusion with a unique load-sharing interface and multiple implant footprints.

INDICATIONS

When the Optio-C Anterior Cervical Plate is used with structural **allograft/autograft**, it is intended for one-level anterior screw fixation of the cervical spine (C2–T1). The implant has been designed for use with structural allograft/autograft to provide stabilization as an adjunct to cervical fusion. Indications for use of the Optio-C Anterior Plate with structural allograft/autograft include degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studes), spondylolisthesis, trauma (e.g., fractures, or dislocations), spinal stenosis, deformity (e.g., kyphosis, lordosis, scoliosis), tumor, pseudarthrosis or failed previous fusion. The Optio-C Anterior Cervical Plate is intended to be used with structural allograft/autograft and with three Optio-C bone screws.

CONTRAINDICATIONS

1. 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.
2. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.
3. Severe osteoporosis is a relative contraindication because it can increase the occurrence of subsidence.
4. Any entity or condition that totally precludes the possibility of fusion, such as, cancer, kidney dialysis or osteopenia, is a relative contraindication.
5. Obesity
6. Pregnancy
7. Certain degenerative disease
8. Foreign body sensitivity
9. 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.
10. Metabolic disorders that can impair bone formation,
11. Inadequate bone stock to support the device,
12. Poor prognosis for good wound healing (e.g., decubitis ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition),
13. Known patient sensitivity to device materials (titanium alloy, Ti-6Al-4V ELI),
14. Use in the posterior elements (pedicles) of the cervical, thoracic or lumbar vertebrae
15. Where attempted correction exceeds the limits of physiologic conditions
16. Any condition not described in the indications for use

See also the WARNINGS and PRECAUTIONS section of this document.

MATERIALS

Implants: The Optio-C Anterior Cervical Plates are manufactured from Titanium alloy (Ti-6Al-4V ELI) per ASTM F-136. Structural Allograft is composed of donated human bone. The structural allograft is regulated as a 361 human cell and tissue product (HCT/P) as defined in US FDA 21 CFR 1271.

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

Trays/Caddies: The Optio-C trays are manufactured from medical grade 304 stainless steel and Radel®. The caddies are manufactured from Radel and polypropylux plastics.

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

WARNINGS

1. Implants and Instruments should be stored in their original packaging in a dry environment, away from aggressive or oily chemicals.
2. 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.
3. 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.
4. During screw insertion, care should be taken to avoid bone screw stripping, which has the potential to cause an unstable screw construct.
5. Care should be taken when handling the flexible instruments. Specifically, the flexible tip should be maintained in the guide to prevent soft tissue damage.
6. When inserting the implant, ensure a tight fit between the inserter and implant. Release distraction before drilling to prevent shifting.
7. 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.
8. 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.
9. Potential risks identified with the use of this device system, which may require additional surgery, include:
   a) Device component fracture,
   b) Loss of fixation,
   c) Non-union,
   d) Neurological injury,
   e) Vascular or visceral injury,
10. Do not use this product for other than labeled indications (off-label use).
11. Components of competitive spinal systems should not be used with the Optio-C Devices.
12. Patient selection shall consider the following factors that are important to the success of the procedure and the performance of the device:
    a) 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.
    b) 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.
    c) 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.
    d) 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 are considered a delaying technique or temporary relief.
    e) Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should be made before material selection or implantation.
    f) Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures in which bone graft is used.
13. Implants can break when subjected to the increased loading associated with delayed union or non-union. Spinal implants are load-sharing 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 also contribute to early failure. Patients should be fully informed of the risks of implant failure.
14. 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.
15. The Optio-C Anterior Cervical Plate is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.
16. The Optio-C Allograft and/or structural allograft/autograft is not to be used alone.
17. The Optio-C Anterior Cervical Plate is not to be used alone, but only with the integrated screws provided and appropriate interbody material per the Indications for Use.

PRECAUTIONS

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

1. Surgical implants must never be reused. An explanted implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns that may lead to early breakage. Reuse of a single-use device that has contacted blood, bone, tissue or other body fluids can lead to patient or user injury. Risks associated with re-use of single-use devices include:
   - Mechanical malfunctions
   - Transmission of infectious agents
2. Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level and other patient conditions that can affect the performance of the system.
3. 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 that it 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.
4. The Optio-C Plate with allograft/autograft 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.
5. The Surgical Technique Guide is not a substitute for training and is for informational purposes only.
6. Carefully read all instructions and be familiar with the Optio-C Anterior Cervical Allograft Interbody System surgical technique before use.

Notes

Notes

Disclaimer: *This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.*

Caution: *Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, adverse effects and patient counseling information.*

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