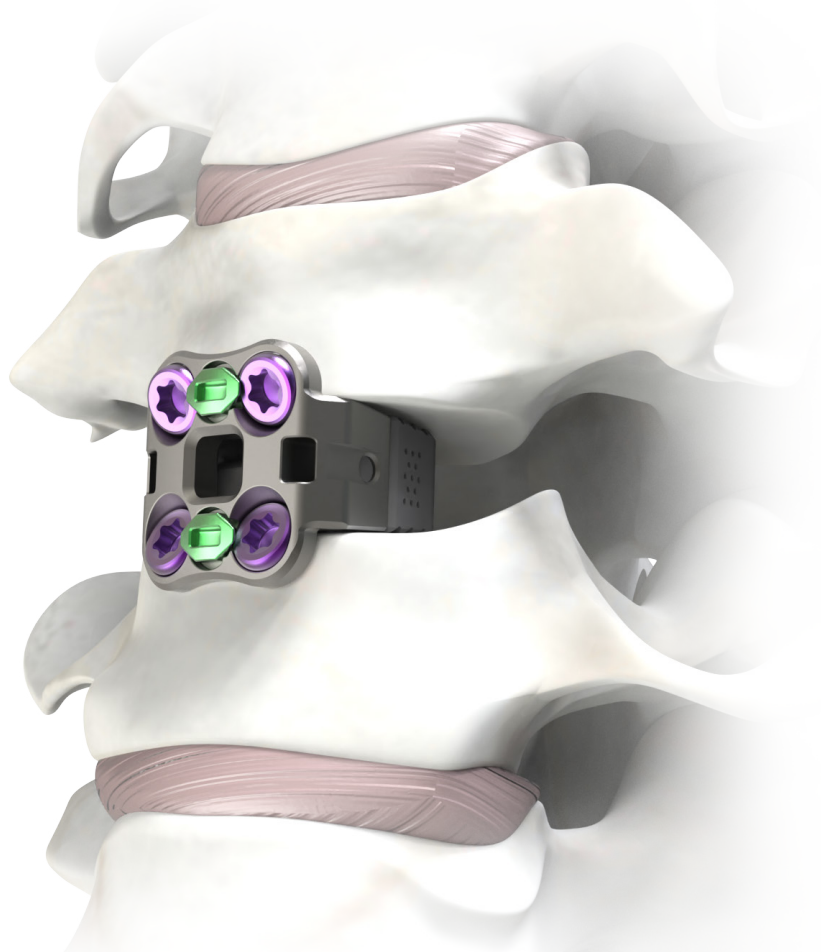
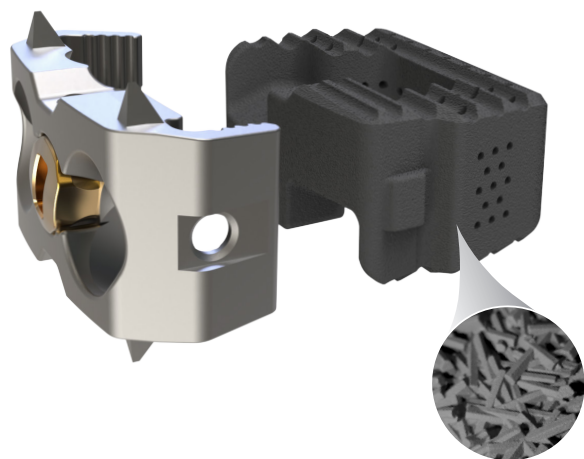


# MONET



## Anterior Cervical Interbody Fusion Cage System



SURGICAL TECHNIQUE GUIDE





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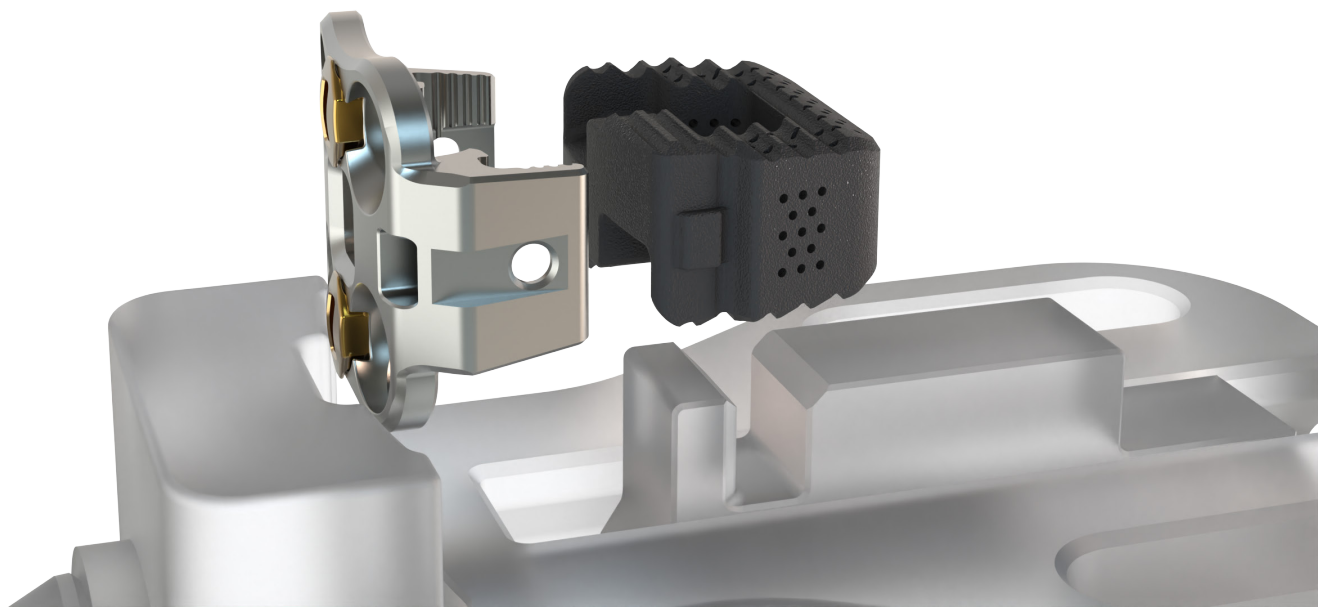
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## PRODUCT OVERVIEW

The MONET NITRO™ Anterior Cervical Interbody Fusion (ACIF) Cage System with the “NITRO” Silicon Nitride Bioactive Technology is designed for intra-operative flexibility. The cage component can be implanted in conjunction with the MONET™ supplemental fixation plates, making it a truly comprehensive ACIF fusion solution.

## SYSTEM FEATURES AND BENEFITS

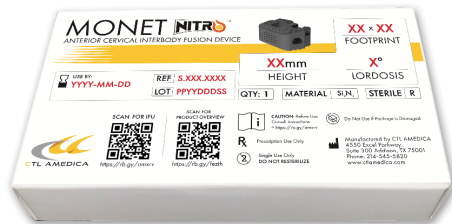
- Proven Biomaterial that increases bone formation which provides an antibacterial properties.
- Proven cage and/or plate modularity design for Operation Room versatility
- Two-hole and four-hole plate configurations accommodate anatomical variation and surgeon preference
- Recessed Torsional stabilizers minimize chance for soft tissue irritation and enhance rotational stability (two-hole plate only)
- Large graft window allows for maximum graft volume
- Robust screw blocking mechanism ensures secure screw placement
- Tapered leading edge of the insertion end of cage for ease of insertion
- Multiple screw options for wide range of insertion trajectory and bone purchase



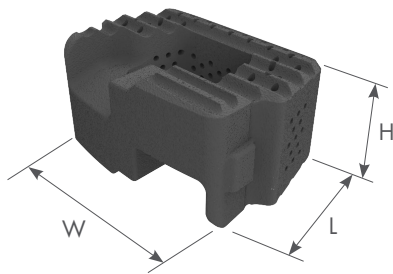


# SYSTEM SPECIFICATIONS

## CAGE & PLATE



Sterile Package



### MONET NITRO™ ACIF Cage (Material: Silicon Nitride)

#### Small

Sterile Part Number	Part Number	Footprint (mm)	Height (mm)
S.213.2225	213.2225	W13 x L9	5
S.213.2226	213.2226	W13 x L9	6
S.213.2227	213.2227	W13 x L9	7
S.213.2228	213.2228	W13 x L9	8
S.213.2229	213.2229	W13 x L9	9
S.213.2230	213.2230	W13 x L9	10

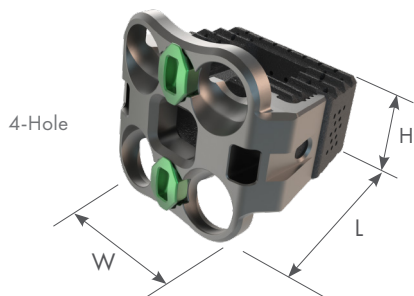
#### Medium

S.213.2325	213.2325	W15 x L11	5
S.213.2326	213.2326	W15 x L11	6
S.213.2327	213.2327	W15 x L11	7
S.213.2328	213.2328	W15 x L11	8
S.213.2329	213.2329	W15 x L11	9
S.213.2330	213.2330	W15 x L11	10

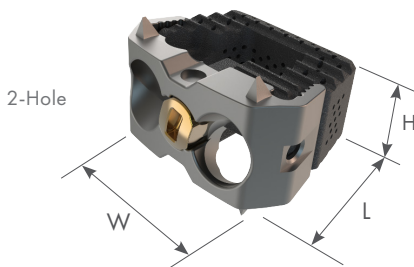
\*Cage heights of 5mm, 11mm and 12mm available upon request  
 \*0°, 6°, 7°, 10°, 12° angle options available upon request

### MONET™ ACIF Plate (Material: Titanium Alloy)

#### Small



4-Hole



2-Hole

2-Hole		4-Hole		Cage & Plate Assembly Footprint (mm)	Height (mm)
Sterile Part Number	Sterile Part Number	Part Number	Part Number		
S.113.1105	S.113.1405	113.1105	113.1405	W15 x L13	5
S.113.1106	S.113.1406	113.1106	113.1406	W15 x L13	6
S.113.1107	S.113.1407	113.1107	113.1407	W15 x L13	7
S.113.1108	S.113.1408	113.1108	113.1408	W15 x L13	8
S.113.1109	S.113.1409	113.1109	113.1409	W15 x L13	9
S.113.1110	S.113.1410	113.1110	113.1410	W15 x L13	10

#### Medium

S.113.1205	S.113.1505	113.1205	113.1505	W17 x L15	5
S.113.1206	S.113.1506	113.1206	113.1506	W17 x L15	6
S.113.1207	S.113.1507	113.1207	113.1507	W17 x L15	7
S.113.1208	S.113.1508	113.1208	113.1508	W17 x L15	8
S.113.1209	S.113.1509	113.1209	113.1509	W17 x L15	9
S.113.1210	S.113.1510	113.1210	113.1510	W17 x L15	10

\*Plate heights of 5mm, 11mm and 12mm available upon request

#### Note:

**Color Coding** - Throughout the MONET NITRO™ Anterior Cervical Fusion System, 2-hole and 4-hole instruments can be differentiated by color. Gold colored instruments indicate usage for 2-hole supplemental fixation plates, while green colored instruments indicate usage for 4-hole supplemental fixation plates.

**Size Definitions** - When referring to sizes, "small and medium" are defined as the following:

**Small:** Cage only footprints of W13 x L9, Assembled cage and plate footprints of W15 x L13

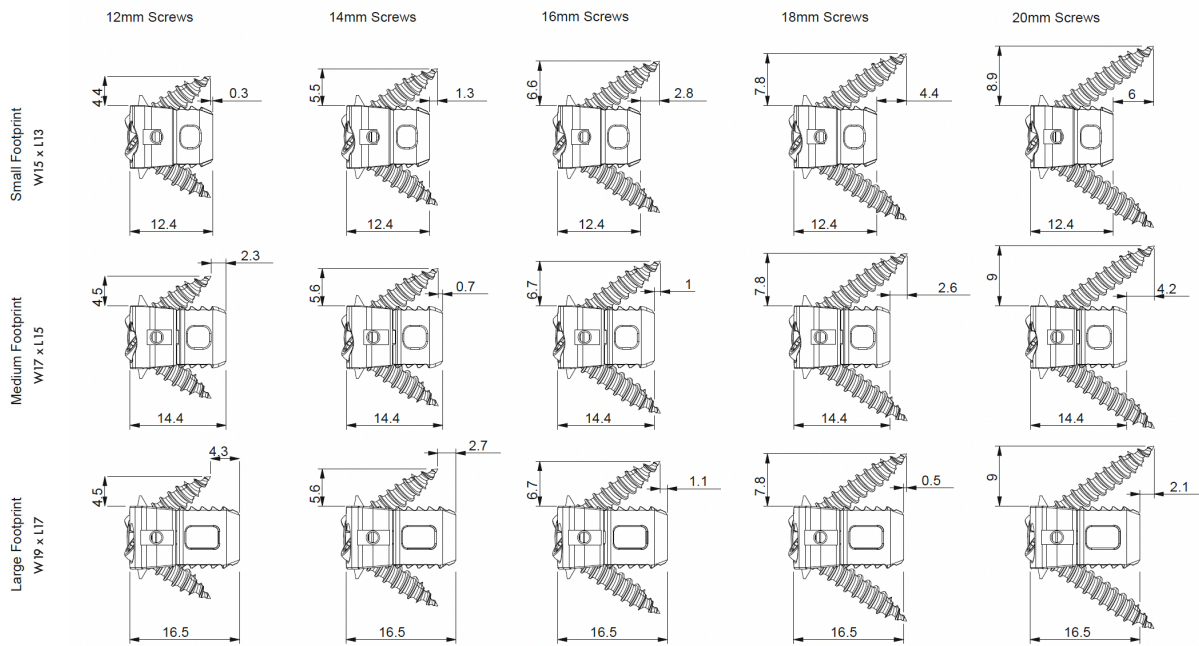
**Medium:** Cage only footprints of W15 x L11mm, Assembled cage and plate footprints of W17 x L15

**Large**(Available upon request): Cage only footprints of W17 x L13mm, Assembled cage and plate footprints of W19 x L17mm

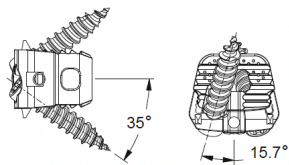
# SCREWS

## ■ Screw Angulations and Measurements

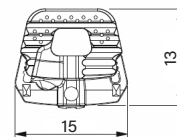
The below reference is for 2-hole supplemental screw angulation and lengths once implanted. Please note that when utilizing 4-hole supplemental fixation options, the full length of the screw will be implanted into the vertebral body. Measurements are in millimeters.



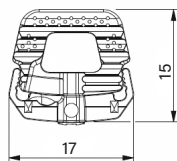
Screw Angulation for 2-Hole Fixation



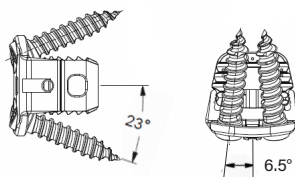
Small Footprint



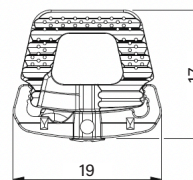
Medium Footprint



Screw Angulation for 4-Hole Fixation



Large Footprint



### Angulation Note:

- Screw angulation remains constant for all two hole plating elements.
- Screw angulation remains constant for all four hole plating elements

## Self-Drilling ACIF Screws

Diameter(mm)	Length(mm)	Color	VARIABLE ANGLE	FIXED ANGLE
			Part Number	Part Number
3.5	12	Blue	113.0112	113.0512
	14	Magenta	113.0114	113.0514
	16	Green	113.0116	113.0516
	18	Purple	113.0118	113.0518
	20	Gold	113.0120	113.0520
4.0	12	Blue	113.0212	113.0612
	14	Magenta	113.0214	113.0614
	16	Green	113.0216	113.0616
	18	Purple	113.0218	113.0618
	20	Gold	113.0220	113.0620



## Self-Tapping ACIF Screws

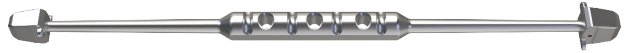
Diameter(mm)	Length(mm)	Color	VARIABLE ANGLE	FIXED ANGLE
			Part Number	Part Number
3.5	12	Blue	113.0312	113.0712
	14	Magenta	113.0314	113.0714
	16	Green	113.0316	113.0716
	18	Purple	113.0318	113.0718
	20	Gold	113.0320	113.0720
4.0	12	Blue	113.0412	113.0812
	14	Magenta	113.0414	113.0814
	16	Green	113.0416	113.0816
	18	Purple	113.0418	113.0818
	20	Gold	113.0420	113.0820

# INSTRUMENTATION

## ■ TRIALS (8°)

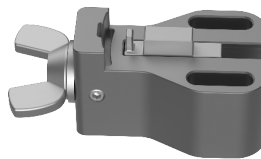
113.7415	ACIF Depth Stop Trial, SM Lordotic, H5/H6
113.7417	ACIF Depth Stop Trial, SM Lordotic, H7/H8
113.7419	ACIF Depth Stop Trial, SM Lordotic, H9/H10
113.7435	ACIF Depth Stop Trial, MD Lordotic, H5/H6
113.7437	ACIF Depth Stop Trial, MD Lordotic, H7/H8
113.7439	ACIF Depth Stop Trial, MD Lordotic, H9/H10

\* 12° trials available upon request



## ■ ASSEMBLY BLOCK

213.7505	Plate-Cage Assembly Block
----------	---------------------------



## ■ AWLS

113.7702	Awl with Sleeve, Angled, AO QC <i>Penetrate vertebral body 12mm if fully inserted</i>
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113.7703	Awl with Sleeve, Variable Angle, AO QC <i>Penetrate vertebral body 12mm if fully inserted</i>
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## ■ DRILLS

113.7722	Drill Bit, D2.3 x L12mm, AO QC, Blue sleeve protector
113.7724	Drill Bit, D2.3 x L14mm, AO QC, Magenta sleeve protector
113.7726	Drill Bit, D2.3 x L16mm, AO QC, Green sleeve protector
113.7728	Drill Bit, D2.3 x L18mm, AO QC, Purple sleeve protector



*Ensure sleeve on distal tip of drill is intact prior to use. Controlled depth can only be achieved with sleeve.*

## HANDLES



100.2011

Straight Handle with Rotary Cap, AO Small QC



113.7509

Modular Handle  
*Used with parts 113.7501, 113.7511, 113.7520, 113.7510 and 113.7602*

## 2-HOLE INSERTERS AND DTS GUIDES



113.7510

2-Hole Plate Lateral Grabber, SM  
*Must be used with part 113.7509 (for use with small footprints and cages of heights 6-12mm)*

113.7511

2-Hole Plate Lateral Grabber, MD  
*Must be used with part 113.7509 (for use with medium footprints and cages of heights 6-12mm)*



113.7520

DTS Guide, 2-Holes, SM-MD  
*Must be used with part 113.7509 (for use with small and medium cages of heights 7-10mm)£*



113.7602

Plate Holder, 2 Holes, Midline

## 4-HOLE INSERTERS AND DTS GUIDES



113.7604

Plate Holder, 4-Holes  
*For use with cages of heights 6-12mm*



113.7600

DTS Guide, 4-Hole

## TAPS



113.7732

Tap, Straight, D3.5 x L20mm, AO QC  
*Penetrates vertebral body 20mm if fully inserted*

## IMPACTORS

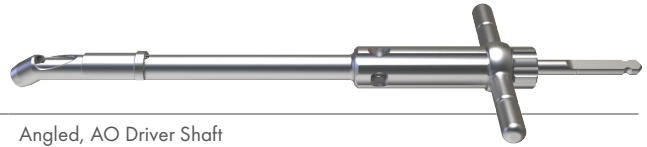


013.7503

Cervical Bone Tamp

## DRIVERS

113.7700



Angled, AO Driver Shaft  
Regular use of surgical instrument lubricant ensures optimal function of the Angled Driver

113.7800



*Image shown out of scale for clarity*

Hexalobular Driver Tip, Short, AO QC Driver, T10

113.7801



*Image shown out of scale for clarity*

Hexalobular Driver Tip, AO QC, T10

113.7712



*Image shown out of scale for clarity*

Drill Tip with Sleeve, L12mm COLOR : Blue

113.7714

Drill Tip with Sleeve, L14mm COLOR : Magenta

113.7716

Drill Tip with Sleeve, L16mm COLOR : Green

113.7718

Drill Tip with Sleeve, L18mm COLOR : Purple

113.7804



Hexalobular Driver, Straight, AO QC, T10

113.7805



Locking Cap Driver, AO QC

## ADDITIONALLY AVAILABLE

113.7508



Modular Handle Adapter

113.7501



Cage Holder-Inserter  
Must be used with part 113.7509  
May ONLY be used with Small/Medium footprints.

113.7741



Modular Flex Tip Driver, AO QC, Long

113.7752



*Image shown out of scale for clarity*

113.7753

Flexible Driver Tip, T10, Small, Short  
Flexible Driver Tip, T10, Small, Long

113.7731



Single Barrel, Drill Guide, Variable

# SURGICAL TECHNIQUE

## POSITIONING AND PREPARATION

### I. SURGICAL APPROACH AND PREPARATION

The MONET NITRO™ instrument set is designed to supplement general instrumentation and a surgeon's current surgical technique. (See Fig. 1)

- Prior to surgery, inspect instruments to ensure a complete set is present and all instruments are functioning.
- Place patient in a supine position for suitable exposure and desired alignment.
- After the anterior vertebral column has been exposed, the longuscolli muscles are elevated and the medial/lateral self-retaining retractor blades are securely positioned beneath them.
- A vertebral body distractor may be used. The distraction pins are positioned midline in the vertebral bodies adjacent to the discectomy. The distractor is placed over the pins and the appropriate amount of distraction is applied. (See Fig. 2)
- Confirm the appropriate disc space and locate the center of disc space by fluoroscopy, ensuring pedicles are equidistant from the spinous processes.

*Note: Distraction set is available upon request.*

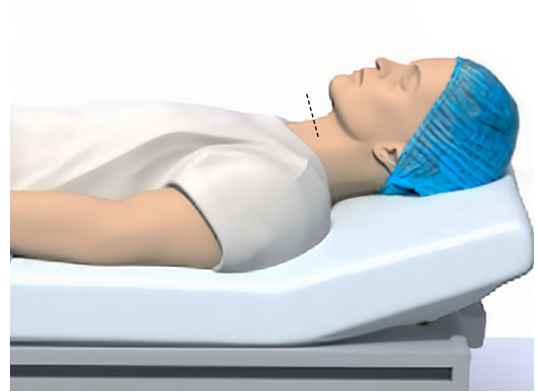


Fig. 1

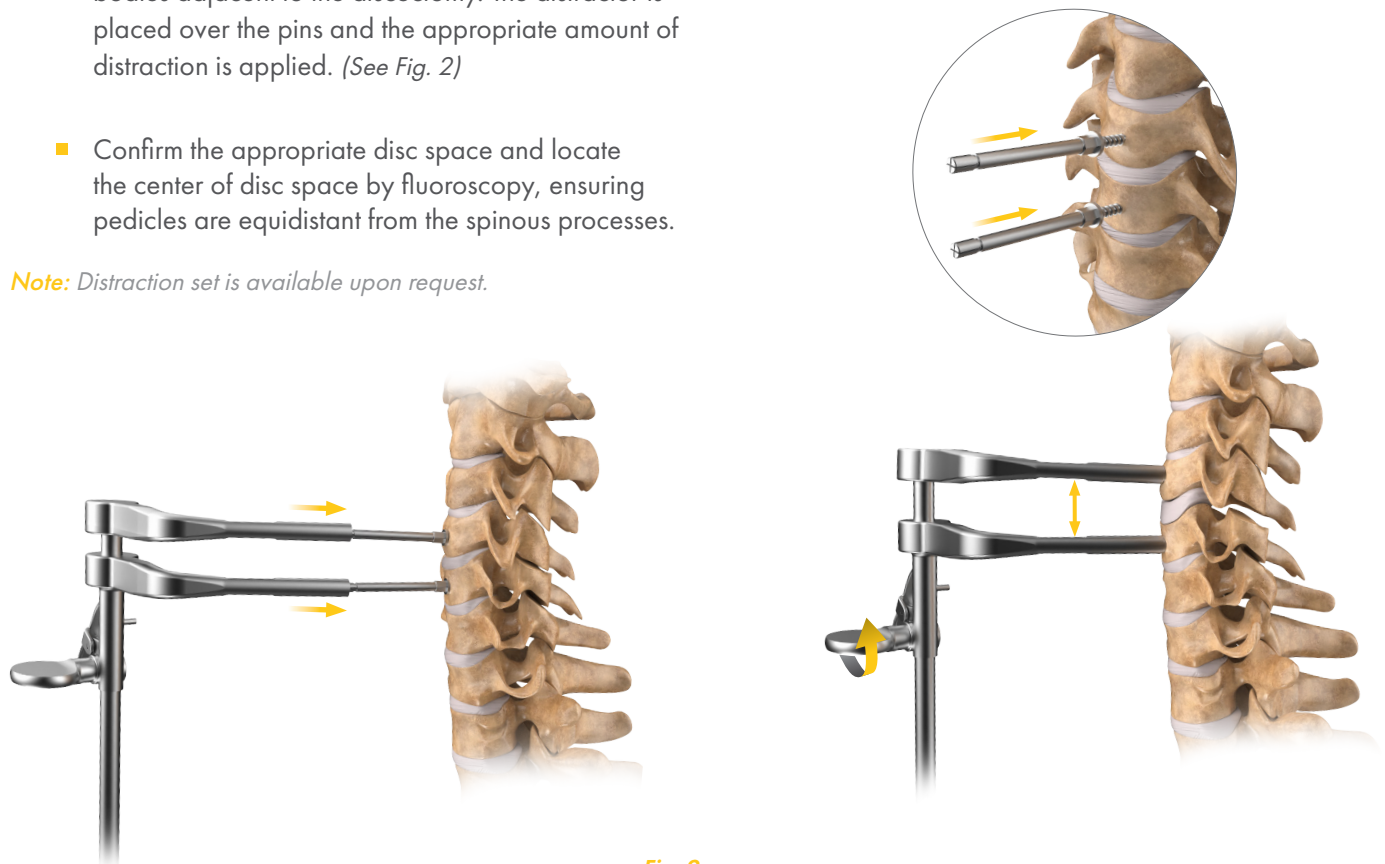


Fig. 2



## II. DISC SPACE PREPARATION

### Step 1

The surgical procedure begins with a complete removal of the cervical intervertebral disc using generic surgical instrumentation. This involves a box-shaped resection of the anterior longitudinal ligament. A small ring curette can be used to remove residual disc material and cartilage to expose the posterior longitudinal ligament. (See Fig. 3)

### Step 2

Thorough removal of the cartilage on the end plates is crucial, ensuring that slight bleeding is observed while maintaining the integrity of the end plates.

### Step 3

Neural structures are decompressed using punches or high-speed milling cutters. If required, any anterior osteophytes or bony changes are addressed during this stage to enhance access to the target segment for implantation.



Fig. 3

## Step 4

Using an ACIF rasp, the superficial layers of cartilaginous endplates can be selectively removed, revealing the underlying bleeding bone. (See Fig. 4)

*Note: Thoroughly preparing the disc space, including meticulous cleaning of the end plates, is crucial for promoting adequate blood supply and achieving successful fusion of the bone. Any harm to the underlying and overlying bone can result in the implant sinking into the vertebral body.*

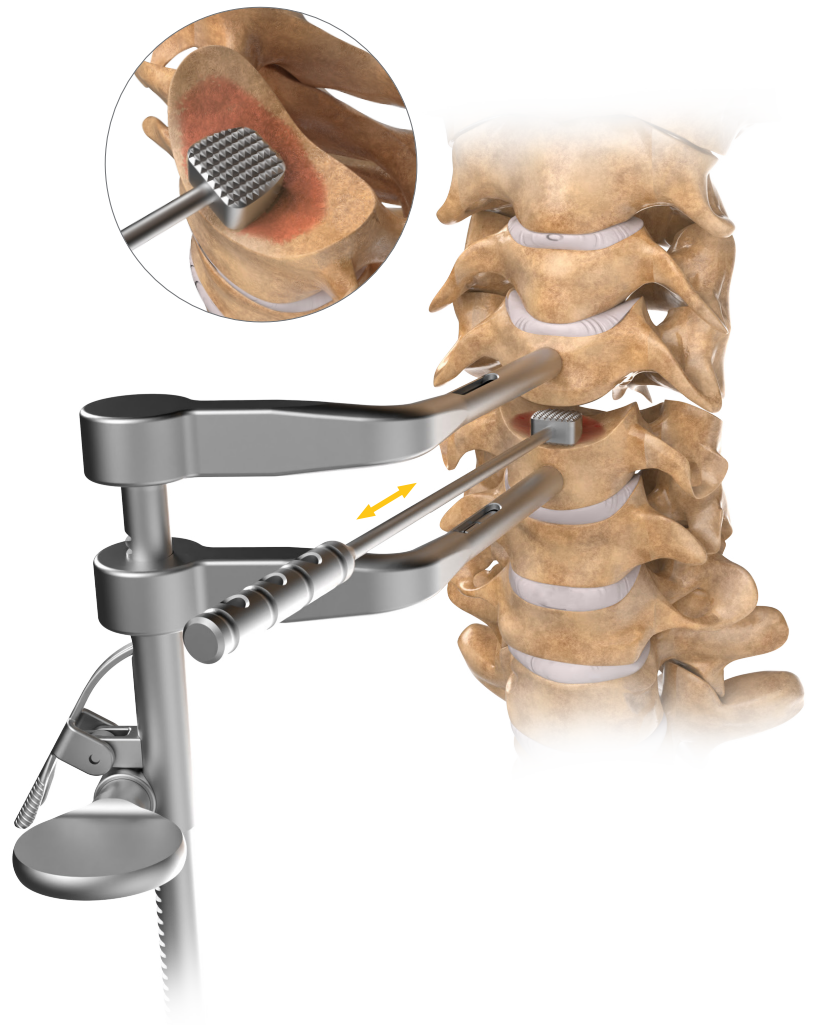


Fig. 4

## III. TRIAL AND IMPLANT SELECTION

### ■ Trial

Determine the size of the required interbody cage by selecting the corresponding trial height, width and depth. (See Fig. 5)

*Note:* Trials are representative of cage size and have been designed to determine height. Trials are also designed to accurately determine sizing with or without supplementary fixation options. Additionally, the stoppers on trials mimic the 4-hole supplemental fixation plate.

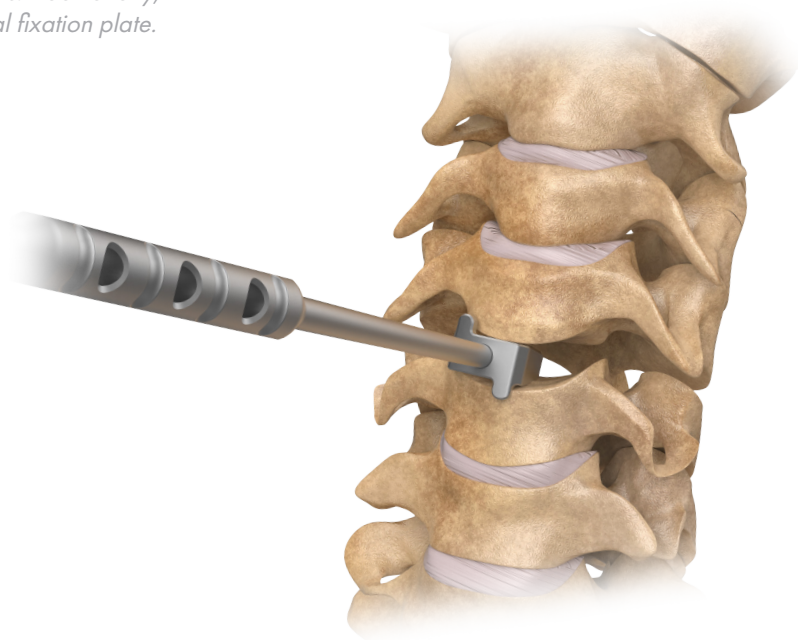


Fig. 5

## IV. INSERTING IMPLANT: CAGE ONLY (OPTION 1)

### Step 1

Thread the Cage Holder-Inserter (113.7501) into a Modular Handle (113.7509) (See Fig. 6) Grab the preferred cage size by centering the prongs to match the grooves on the outside of the cage and turning the proximal knob of the modular handle clockwise. (See Fig. 7)



Fig. 6



Fig. 7

### Step 2

Insert the cage into the prepared disc space. (See Fig. 8)

**Note:** Tamping the cage without supplemental fixation is not recommended. For correcting cage placement, tap the Cage Holder-Inserter to gently position the cage in the correct location between the vertebral bodies.

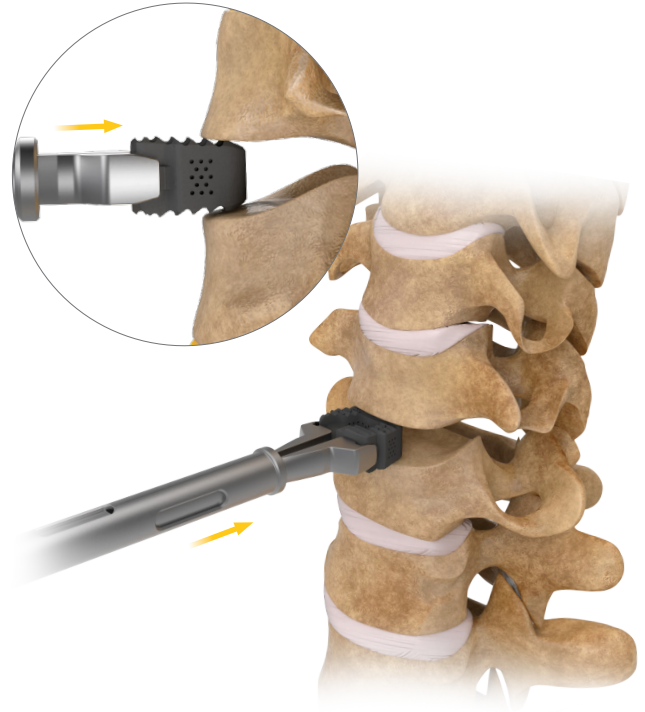


Fig. 8

### Step 3

Disengage the Cage Holder-Inserter from the cage by rotating the proximal knob of the modular handle counter-clockwise. (See Fig. 9)

**Note:** If necessary use the Modular Handle Adapter (113.7508) to disengage the Cage Holder-Inserter.



### Step 4

Remove the inserter leaving the cage in place.

Fig. 9

### Step 5

Use Cervical Bone Tamp (013.7503) to make any necessary adjustments in the placement of the cage while gently tapping with a mallet. (See Fig. 10)

**Note:** The tamp should only be used when inserting cage and plate assembly.

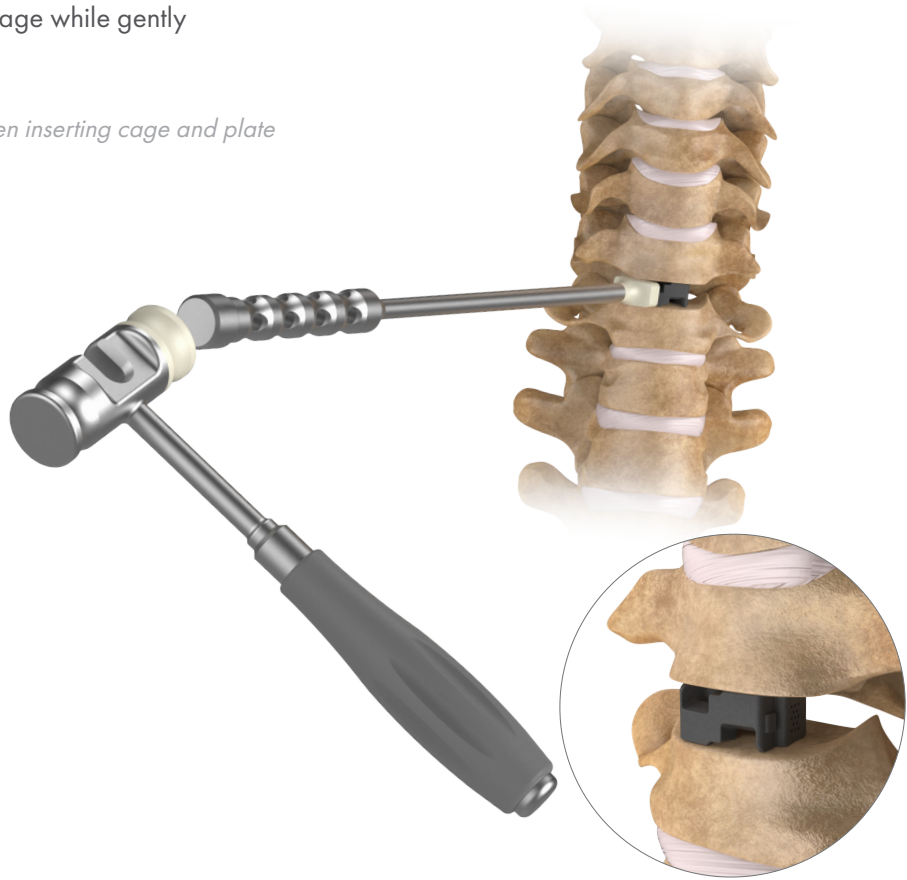


Fig. 10



## VI. INSERTING IMPLANT: CAGE AND PLATE (OPTION 2)

### ■ Assembling the Cage and Supplemental Fixation Plate

#### Step 1

Place the preferred supplemental fixation plate into the designated slot on the Plate-Cage Assembly Block (213.7505) with the face of the plate facing the knob of the assembly block. (See Fig. 13)

**Note:** 4-hole plate is shown as reference. Instructions for assembling cage and supplemental fixation plates are consistent for both 2-hole and 4-hole plating options.

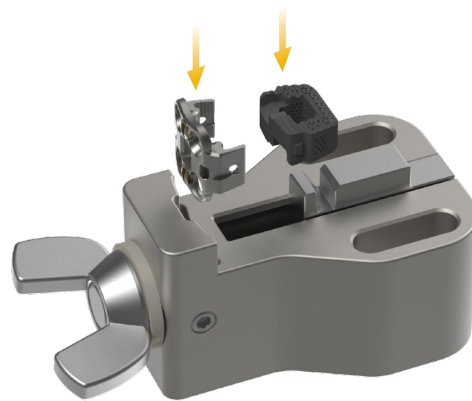


Fig. 13

#### Step 2

Place the posterior wall of the corresponding cage between the two vertical ridges on the Plate-Cage Assembly Block. The anterior side of the cage should face both the selected plate and the knob. (See Fig. 14)

**Note:** Cage and plate sizing is not variable. Cage height must remain consistent with Supplemental Plate options.



Fig. 14

#### Step 3

Turn the knob clockwise to begin engaging the cage and plate. Continue turning the knob clockwise until the cage and plate are fully engaged. A tactile click may be felt. **Ensure fixation by confirming visually.** (See Fig. 15)

**Caution:** Once assembled, the cage cannot be disassembled from the supplemental fixation plate without causing permanent damage to implants. Improperly assembled cages and plates should not be used or implanted.

**Caution:** Caution: Upon achieving close contact, stop turning the knob. Forcing beyond contact may damage the implant.



Fig. 15

#### Step 4

Turn the knob one quarter-turn counter-clockwise to remove the assembled plate and cage from the Plate-Cage Assembly Block. (See Fig. 16)

**Caution:** Continuing to turn the knob of the assembly block counter-clockwise, prior to removing the assembled cage and supplemental fixation plate, can result in partial disassembly of the device.

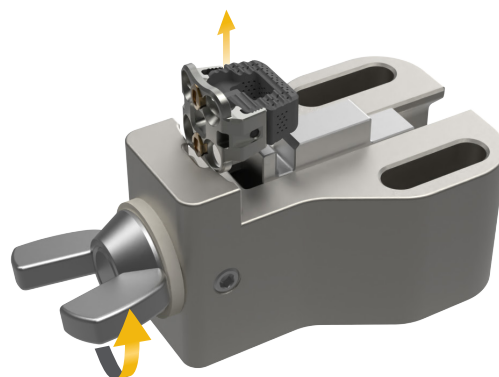


Fig. 16





## ■ Inserting Cage with 2-Hole Assembly

The following plate holder options are available for use with 2-Hole Supplemental Fixation Plates:

- 2-Hole Plate Holder with DTS Guide (113.7520)
- 2-Hole Plate Lateral Holder (113.7511)
- Plate Holder, 2 Holes, Midline (113.7602)

**Note:** All 2-hole plate holders must be assembled with the Modular Handle (113.7509) prior to use.

### Step 1

#### Option A - Using DTS Guide

Attach the plate by centering the plate holder to match the grooves on the top and bottom sides of the plate. Once seated, turn the end of the modular handle clockwise until secure. (See Fig. 17)

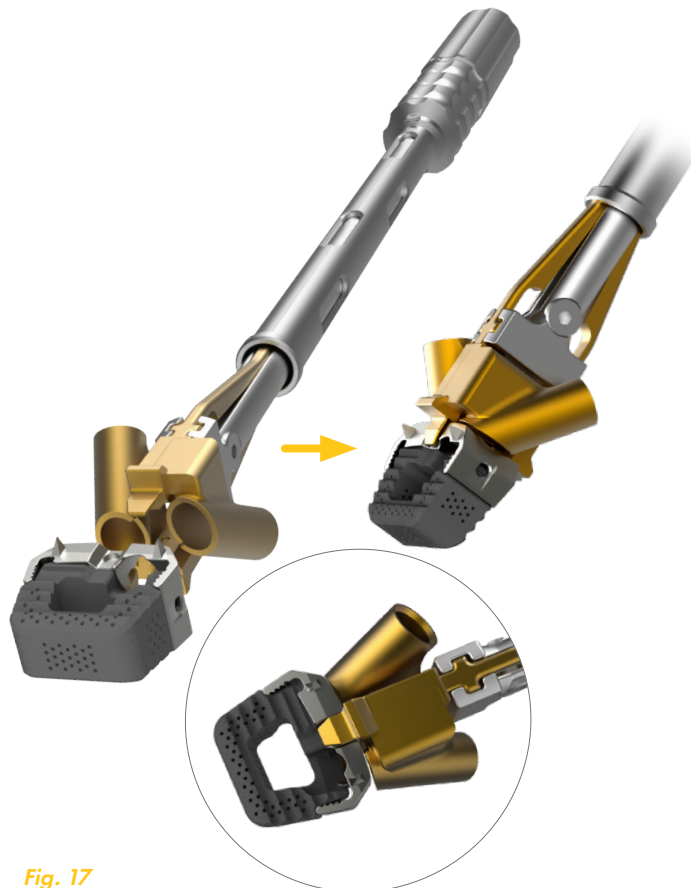


Fig. 17

#### Option B - Using Lateral Holder

Attach the plate by centering the plate holder to match the grooves on the lateral sides of the plate. Once seated, turn the end of the modular handle clockwise until secure. (See Fig. 18)

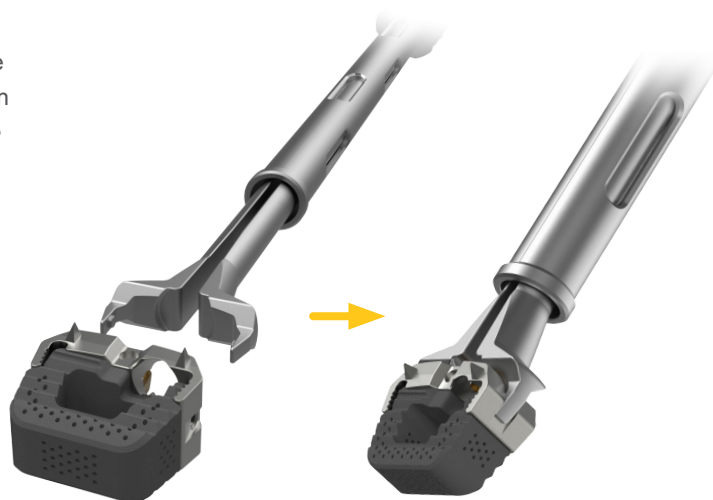


Fig. 18

### Option C - Using Midline Holder

Attach the plate by centering the plate holder to match the grooves on the top and bottom sides of the plate. Once seated, turn the end of the modular handle clockwise until secure. (See Fig. 19)

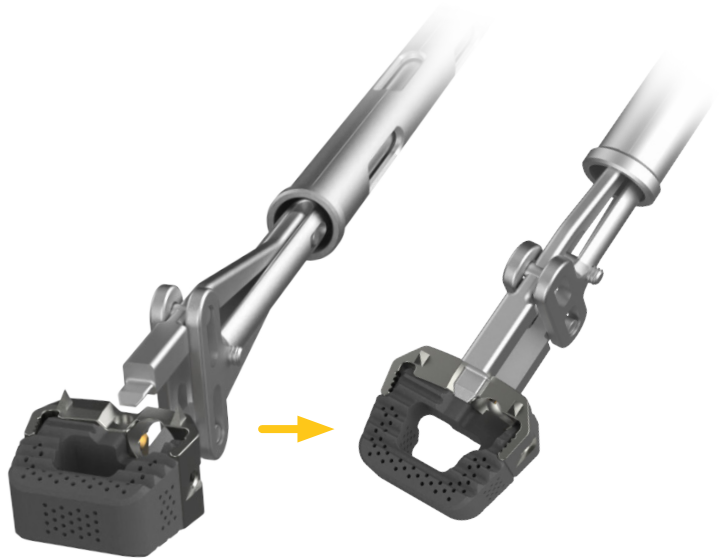
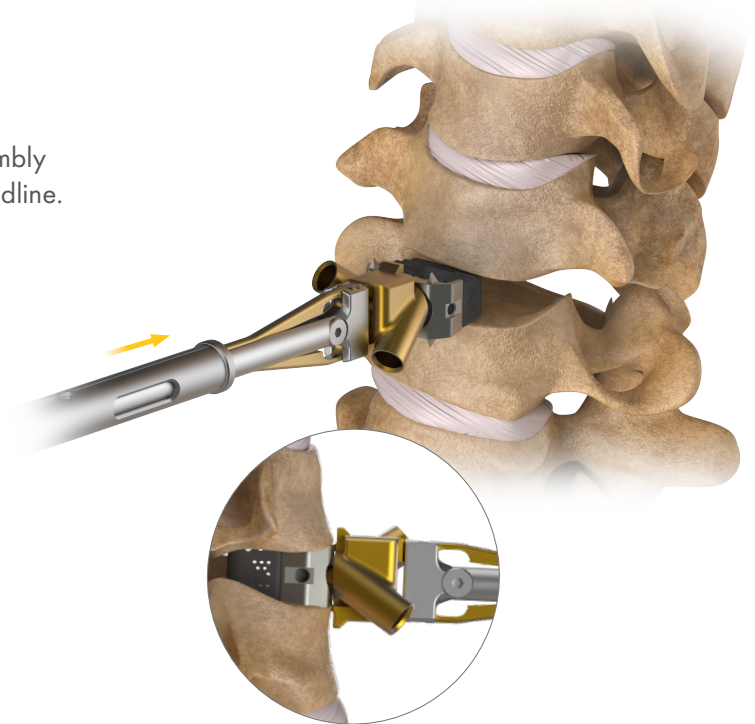


Fig. 19

### Step 2

Insert the cage with supplemental fixation plate assembly into the prepared cervical disc space, centering to midline. (See Fig. 20)



**Note:** For Screw insertion, go to the following sections:

- Section VII Preparing Screw Pilot Holes
- Section VIII Screw Insertion

Fig. 20

### Step 3

Disengage the 2-Hole Plate Holder from the Plate by rotating the proximal knob of the modular handle counter-clockwise.

### Step 4

At final placement after screw insertion, ensure the face of plate is flush with the anterior profile of the vertebral bodies. **Torsional stabilizers on 2-hole plates should be fully implanted into the disc space and not be visible outside of the vertebral body. Confirm with fluoroscopy. (See Fig. 21)**

**Note:** Fluoroscopy may be used at any point to verify cage and plate placement, and is recommended after cage placement to confirm correct positioning. PEEK cages include tantalum markers for fluoroscopic confirmation of placement. Location of lateral tantalum markers are at the midpoint of chosen cage height. Fluoroscopy can also provide visual confirmation that the plate's torsional stabilizers are anchored into bony anatomy.

**Caution:** Dependant upon patient anatomy and disc preparation technique, please note that the assembly may advance an additional 2-3mm into the disc space upon screw insertion.



Fig. 21

## ■ Inserting Cage with 4-Hole Assembly

### Step 1

Prior to engaging the plate ensure the proximal knob of the 4-Hole plate holder (113.7604) is turned counter-clockwise.

### Step 2

Engage the plate by placing the center prong into the center plate window, ensuring the outer prongs lock into the appropriate plate notches, and turn the proximal knob of the inserter clockwise. (See Fig. 22)

*Note:* The inserter should attach rigidly to the supplemental fixation plate.



Fig. 22

### Step 3

Insert the cage with supplemental fixation into the prepared cervical disc space, centering to midline. (See Fig. 23)

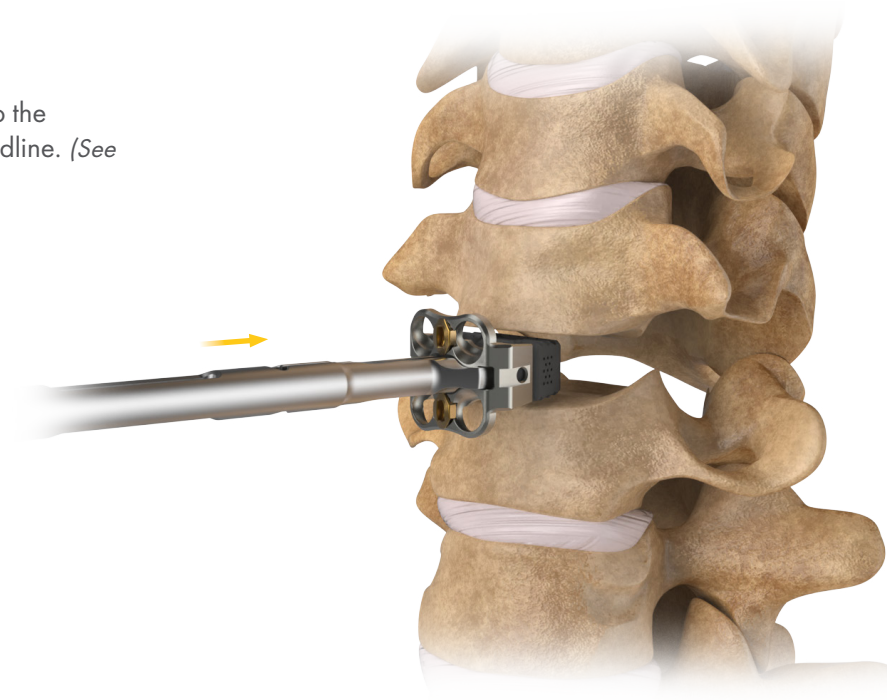


Fig. 23

### Step 4

Ensure the face of the plate rests on the anterior profile of the vertebral bodies. (See Fig. 21)

*Note:* Fluoroscopy may be used at any point to verify cage and plate placement and is recommended after cage placement to confirm correct positioning.

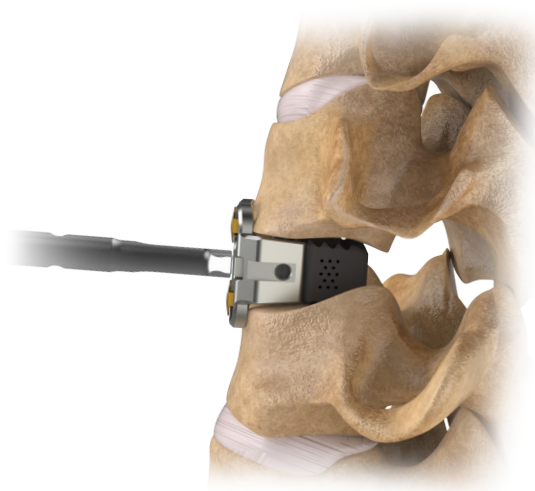


Fig. 21

### Step 5

Turning the proximal knob counter-clockwise, remove the inserter from the implanted assembly. (See Fig. 22)

*Note:* 4-hole inserters should be removed prior to insertion of screws.

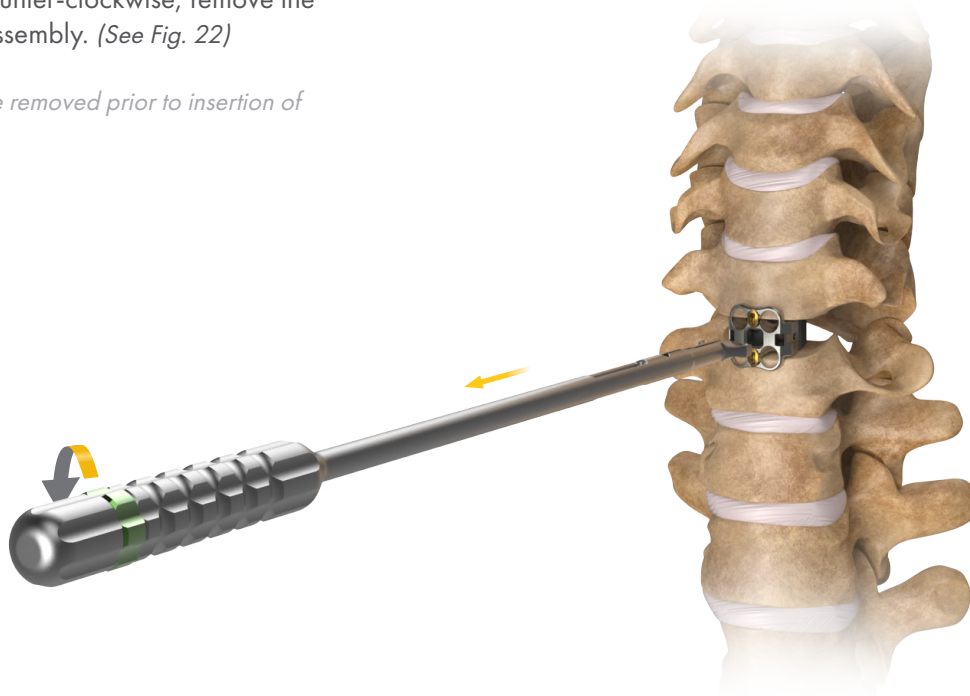


Fig. 22

## VII. PREPARING SCREW PILOT HOLES

Inserters for 2-hole plates may be left in place when preparing the screw holes and are able to accommodate awls, straight and angled drills and drivers.

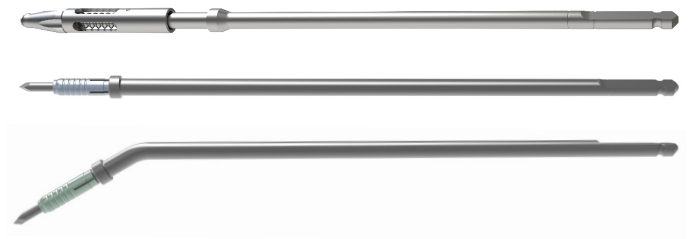
Lateral inserters and 4-hole inserters should be removed prior to screw insertion. Fluoroscopy is recommended prior to preparing screw holes to confirm cage placement.

### ■ Awling and Drilling

#### Step 1

Awls, taps and drills are available and compatible with all 2-hole inserter options. 4-hole inserters should be removed prior to screw insertion

**Note:** Ensure the sleeve protector is fully covering the distal tip of the drill or awl prior to use.



#### Step 2

Prepare pilot holes with awls and/or drills to your preferred trajectory. (See Fig. 23)

**Note:** The sleeve protector will automatically retract during use and will stop advancing at the depth indicated on each awl/drill.

**Note:** A 4-Hole DTS Guide (113.7600) is available for guidance if desired.

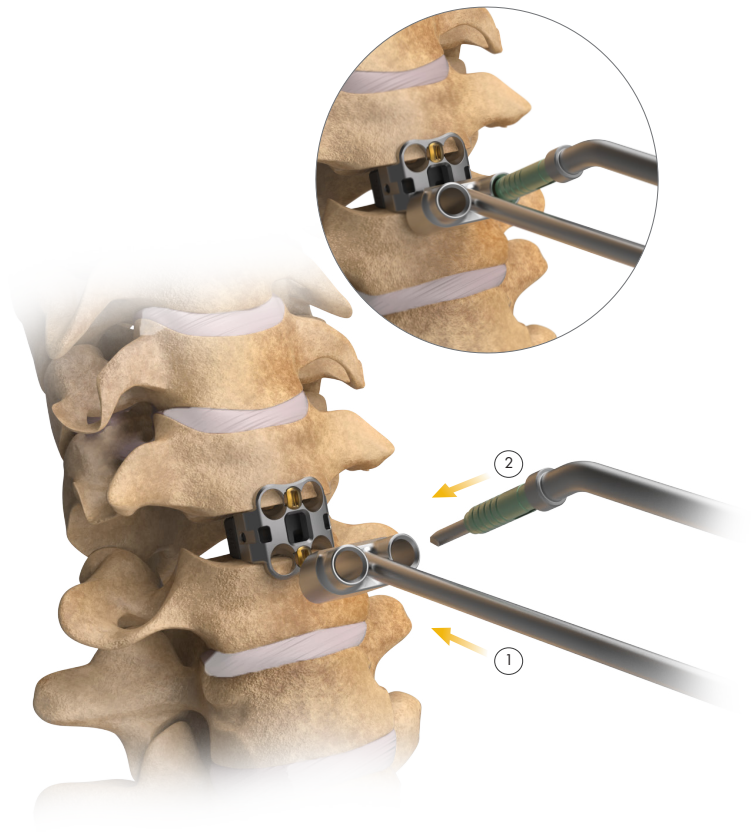


Fig. 23



## VIII. SCREW INSERTION

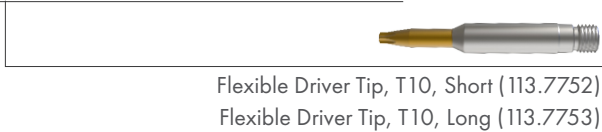
The following driver options are available:

- **Hexalobular Straight Driver (113.7804)**
- **Hexalobular Angled Driver (113.7700)**



**Note:** The hexalobular angled driver must be used with either part 113.7800 or 113.7801 and must be assembled prior to use.

- **Modular Flex Tip Driver (113.7741)**



**Note:** The flex driver must be used with either part 113.7752 or 113.7753 and must be assembled prior to use.

### ■ Assembling the Angled Driver (113.7700)

#### Step 1

Pull back protective shield. (See Fig. 24) (1)

#### Step 2

Rotate thumb wheel on proximal end counter clockwise to move center shaft and pull the center shaft back. (See Fig. 24) (2)

#### Step 3

Place the Hexalobular Driver Tip (113.7800 or 113.7801) or Drill Tip with Sleeve (113.7712, 113.7714, 113.7716 or 113.7718) in the tip of the driver. (See Fig. 24) (3)

#### Step 4

Push inner shaft until it mates with the driver or drill tip and rotate thumb wheel on proximal end clockwise to lock center shaft. (See Fig. 24) (4)

#### Step 5

Push protective shield to cover gear mechanism. (See Fig. 24) (5)

**Note:** Regular use of surgical instrument lubricant ensures optimal function of the angled driver.

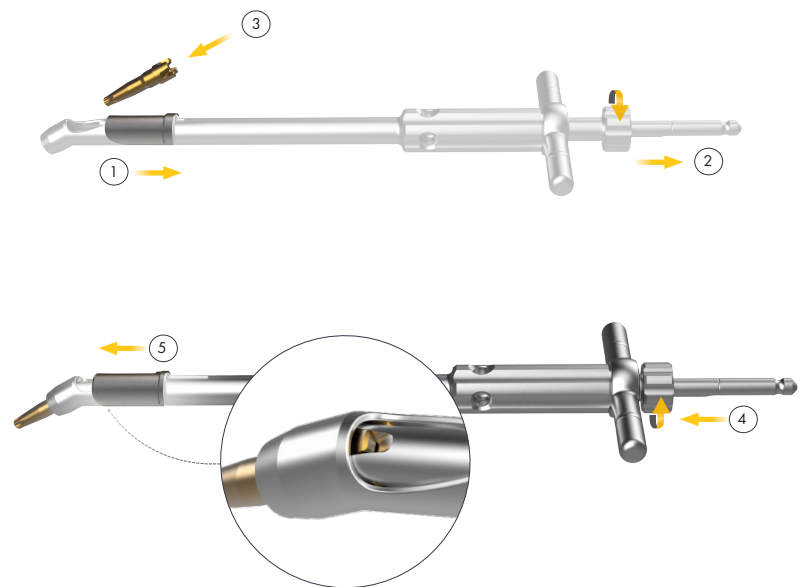


Fig. 24



## ■ Assembling the Flex Driver (113.7741)

### Step 1

Insert the flexible driver tip into the Modular Flex Tip Driver (113.7741) (See Fig. 25)

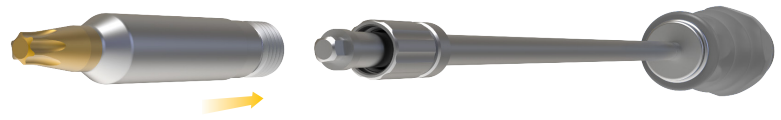


Fig. 25

### Step 2

Thread the Modular Flex Tip Driver onto the flexible driver tip by turning proximal tip counter-clockwise. (See Fig. 26)

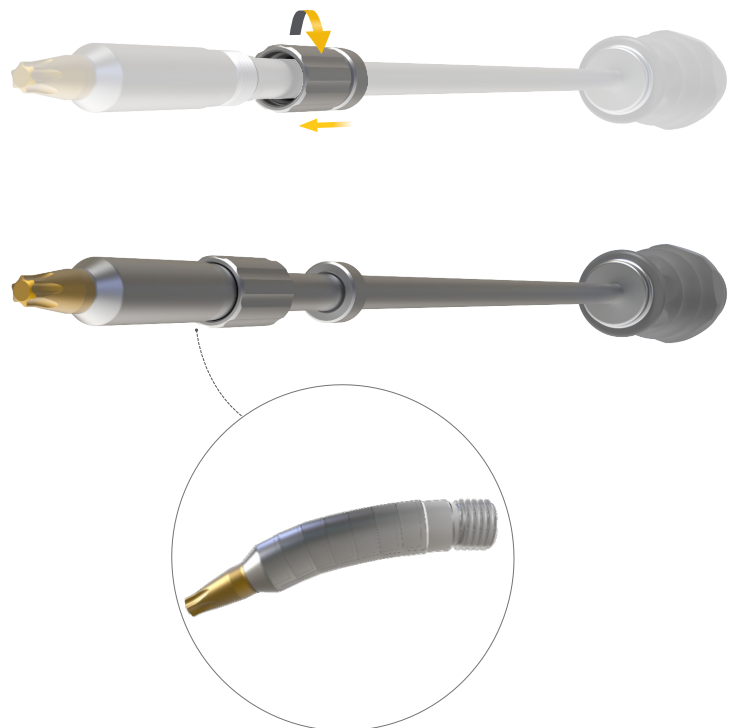


Fig. 26

## ■ Inserting Screws

### Step 1

Using preferred driver, insert the appropriate screw configuration, following the trajectory of the pilot hole.  
(See Fig. 27)

*Note:* If desired, screws can be inserted through any DTS guide (i.e. 2-Hole Plate and 4-Hole Plate DTS Guide) (See Fig. 28)

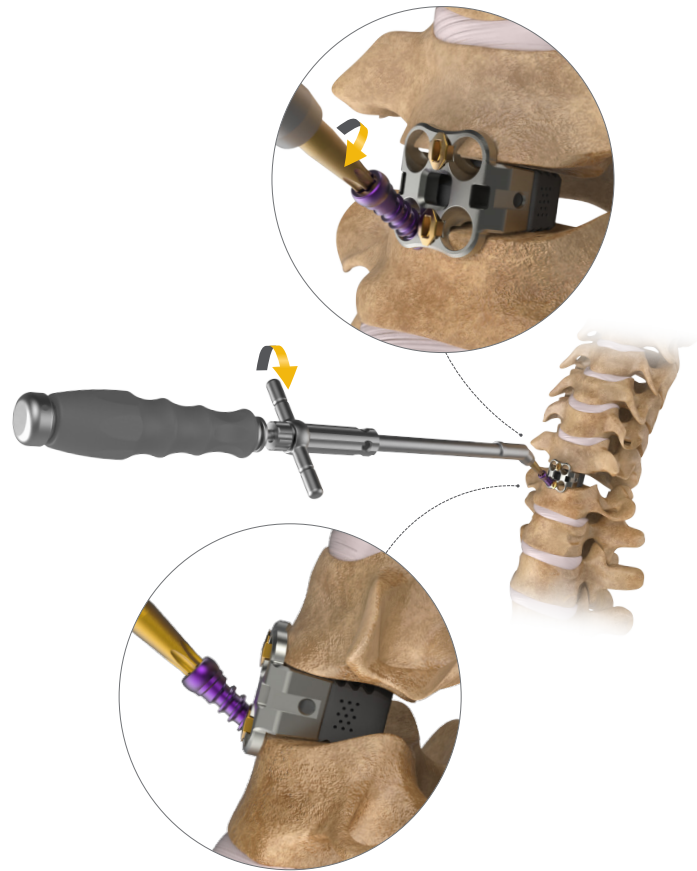
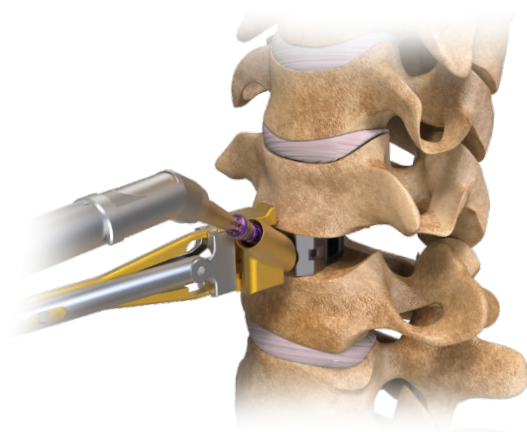
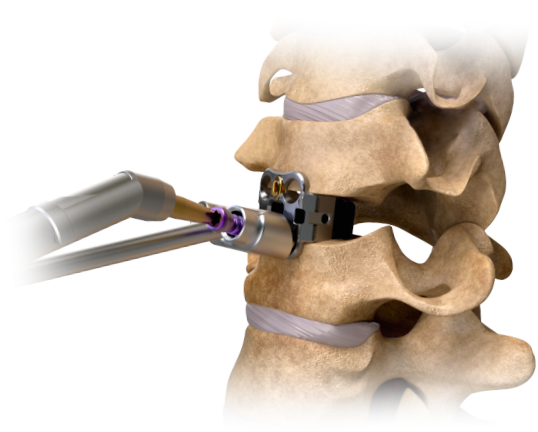


Fig. 27



DTS Guide, 2-Hole Plate



DTS Guide, 4-Hole Plate

Fig. 28

## Step 2

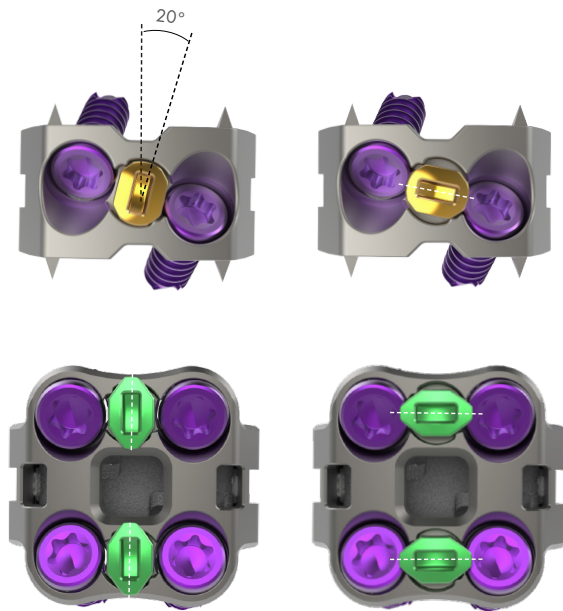
Repeat as necessary.

## Step 3

After all screws are placed, if using a 2-Hole plate holder, remove the chosen inserter by unscrewing the proximal knob counter-clockwise.

## Step 4

To engage the locking mechanism, attach the **Locking Cap Driver (113.7805)** to the **AO QC Handle (100.2011)**. Turn the locking mechanism 90 degrees clockwise to engage the lock. Confirm visually. (See Fig. 29)



a) unlocked position

b) locked position

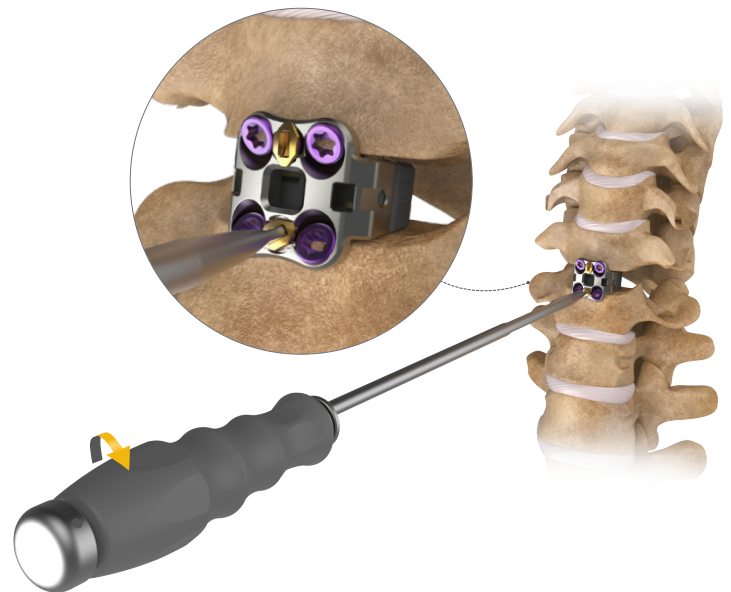


Fig. 29

## IX. IMPLANT REMOVAL

### ■ CAGE ONLY

#### Step 1

Engage the Cage Holder-Inserter to the cage by rotating the proximal knob of the modular handle clockwise. (See Fig. 11)



Fig. 11

#### Step 2

Pull the implant out of the disc space (See Fig. 12)



Fig. 12

## ■ CAGE AND PLATE

### Step 1

Unlock the locking mechanism by turning it 90 degrees counter-clockwise. (See Fig. 30)

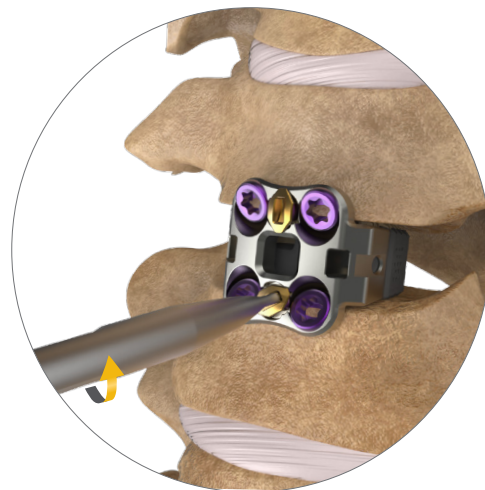


Fig. 30

### Step 2

Remove the screws using the preferred driver. (See Fig. 31)

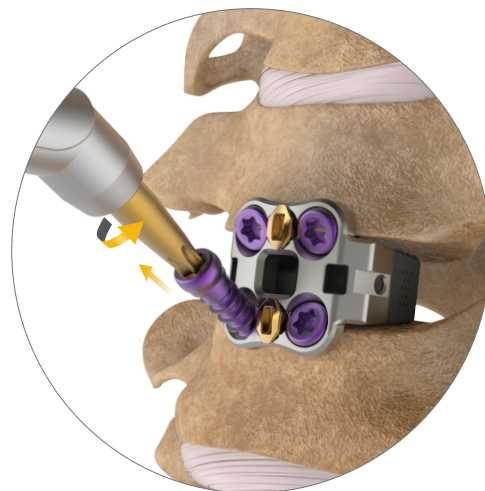


Fig. 31

### Step 3

Engage the plate using the appropriate plate holder. (See Fig. 32)

*Note:* For plate holder options, please refer to previous sections.

### Step 4

Pull the implant assembly out of the disc space. (See Fig. 32)

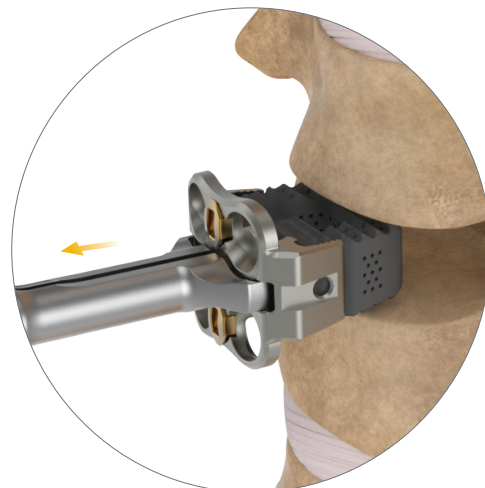


Fig. 32







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