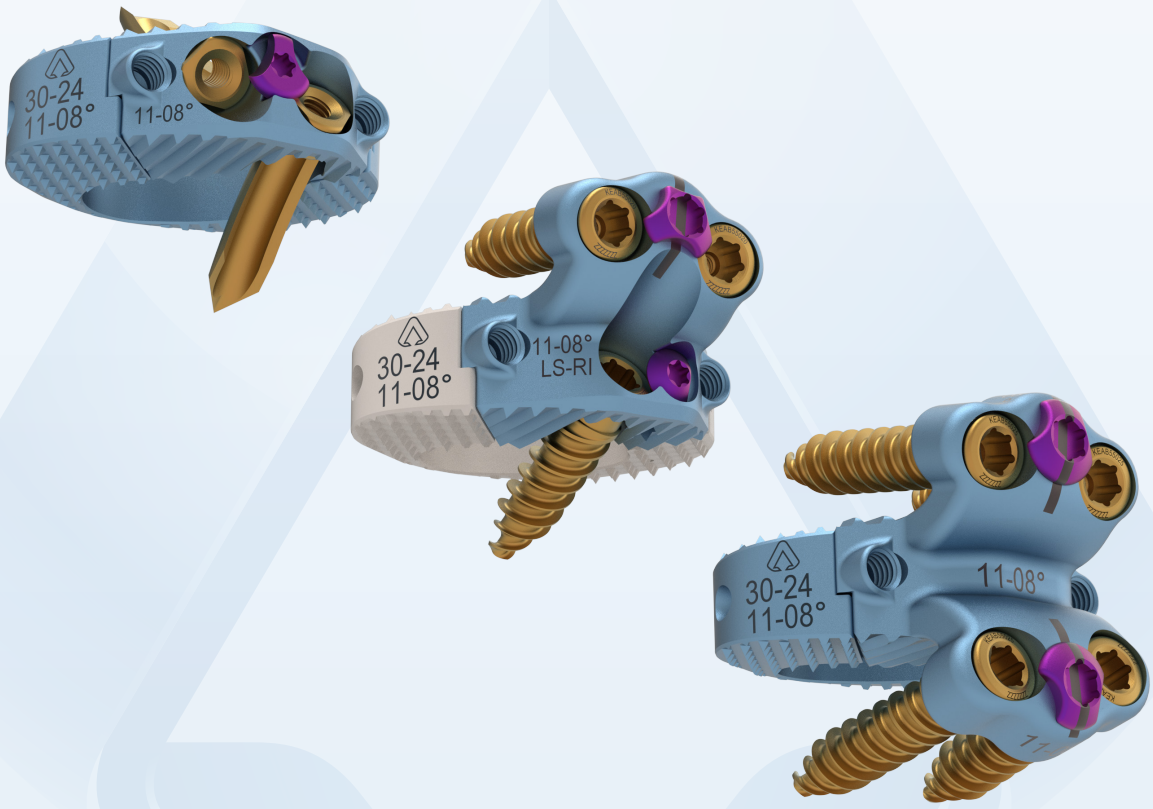
EL CAPITAN

OBLIQUE ANTERIOR LUMBAR INTERBODY FUSION

ASTURA MEDICAL

DESIGN RATIONALE

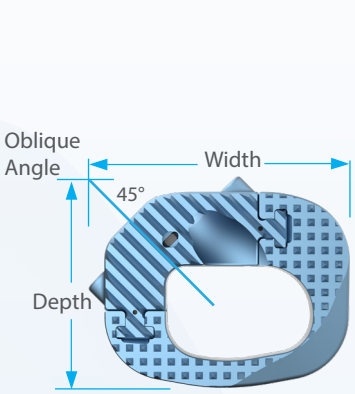
The El Capitan Oblique Anterior Lumbar Interbody Fusion System is a comprehensive system that provides a complete range of anatomic spacers, plates, and fixation options for rigid oblique anterior lumbar stabilization. The system's intuitive design provides the versatility to accommodate either a left or right-sided approach to address a wide array of anatomical challenges to ensure an efficient, streamlined sequence.



ASTURA MEDICAL

SPECIFICATIONS

SPACER SIZING			
TYPE	FOOTPRINT (MM)	HEIGHTS (MM)	LORDOSIS (DEG)
HA PEEK Spacer	30x24, 34x26, 38x28, 42x28	11,13,15,17,19, 21	8°, 15°, 20°
Acid-Etched Titanium Spacer	30x24, 34x26, 38x28, 42x28	11,13,15,17,19, 21	8°, 15°, 20°



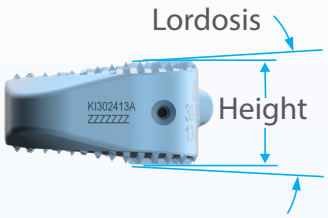
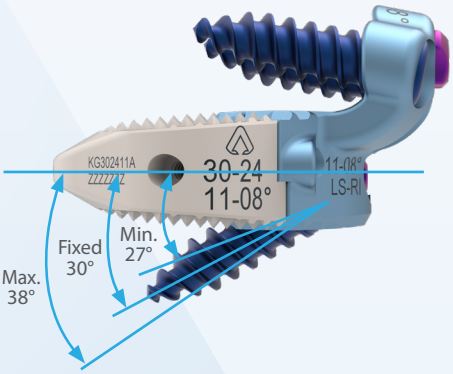
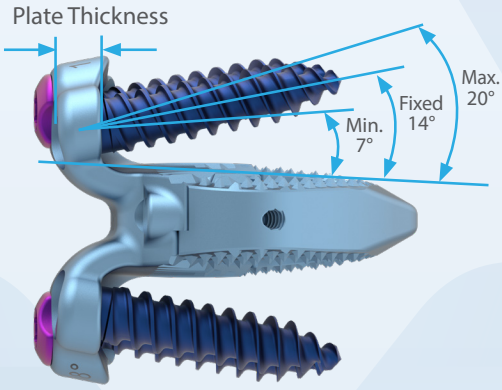
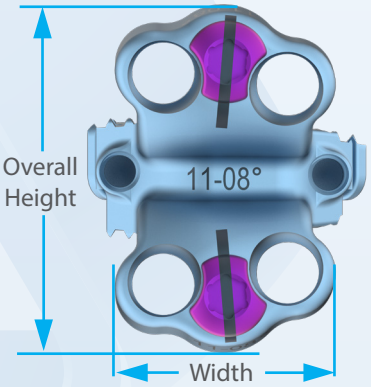


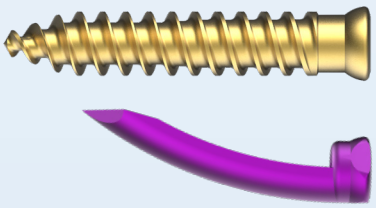
PLATE TYPES AND SIZING				
TYPE	SPACER HEIGHT (MM)	OVERALL HEIGHT (MM)	WIDTH (MM)	THICKNESS (MM)
Zero	11,13,15,17,19, 21	Spacer Height	25	N/A
Half	11,13,15,17,19, 21	21, 23, 25, 27, 29, 31	25	3
Full	11,13,15,17,19, 21	31, 33, 35, 37, 39, 41	25	3







FIXATION TYPES AND SIZING			
TYPE	CONSTRAINT	DIAMETERS (MM)	LENGTHS (MM)
Self-Drilling Screws	Variable	5.0 or 5.5	20, 25, 30
Nails	Variable	5.5	20, 25, 30

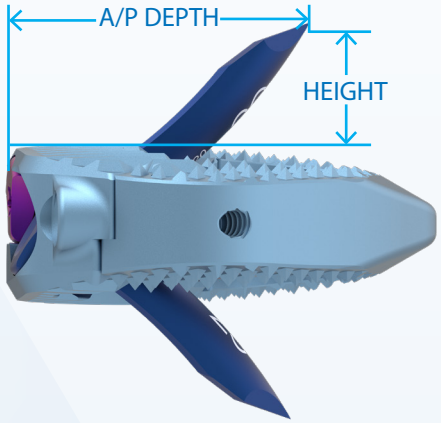


NAIL AND SCREW SIZING

*****Warning: Screws and Nails not to exceed the Max Lengths for the Sizes Designated Below*****

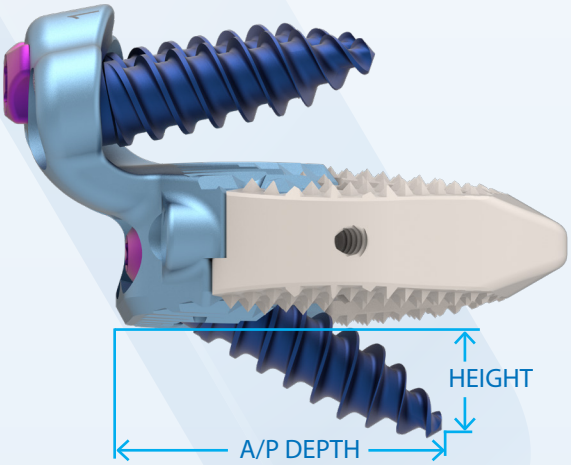
ZERO PLATE

SPACER SIZE	MAX NAIL LENGTH	MAX SCREW LENGTH
30X24	25mm	20mm
34X26	30mm	25mm
38X28	30mm	30mm
42X28	30mm	30mm



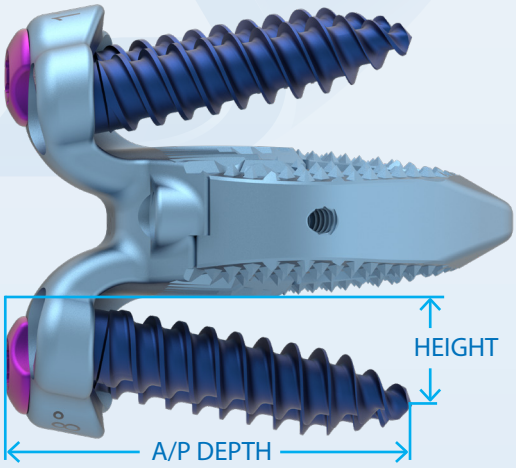
HALF PLATE (ZERO PROFILE BORE)

SPACER SIZE	MAX SCREW LENGTH
30X24	20mm
34X26	25mm
38X28	30mm
42X28	30mm



FULL PLATE

SPACER SIZE	MAX SCREW LENGTH
30X24	20mm
34X26	25mm
38X28	30mm
42X28	30mm



1.0 PATIENT POSITIONING

1.1 Position the patient laterally on either their left or right side depending on the desired approach direction.

2.0 ACCESS

2.1 Using fluoroscopy, verify the operative level. Using a surgical pen, mark the desired skin incision location approximately midway between the patient's coronal and sagittal plane.

2.2 Approach the disc through the marked area using a standard anterior retractor system.

2.3 To verify the retraction is sufficient, connect multiple Trials (KZF02XXXX) to the Trial Inserter (KZF020000) (shown on next page) and approach the operative level.

2.4 If desired, the Modular Rotating Distractor (KZA170000) may be used to insert or remove a Midline Marking Pin (KZA010000) to assist in anatomic orientation.

3.0 DISC PREPARATION

3.1 Incise the disc using the Annulotomy Knife (KZA030000) to create a rectangular channel matching the chosen Trial size.

3.2 Utilize the Pituitary's (KZA09SQXX) and Lexcel (KZA060000) to begin removing the disc material from the intervertebral space.

3.3 Utilize the Osteotome (KZA11SZXX) or Cobb (KZA12SZXX) to assist in removing intervertebral disc material.

3.4 Utilize the Kerrisons (KZA10SZXX) to perform the necessary bone removal.

3.5 Utilize Currettes (KZA14SQXX) and Rasps (KZA13SRXX) to complete the endplate preparation.

3.6 The Modular Rotating Distractors (KZA1800XX) can be used to maintain disc height during the discectomy process. Attach the desired height Rotating Distractor (KZA1800XX) to the Modular Rotating Distractor Handle (KZA170000). Placing it into the disc place, then rotating it 90 degrees to distract the end plates. Once the desired height is achieved, the Modular Rotating Distractor Handle (KZA170000) can be removed to provide additional space and visualization.

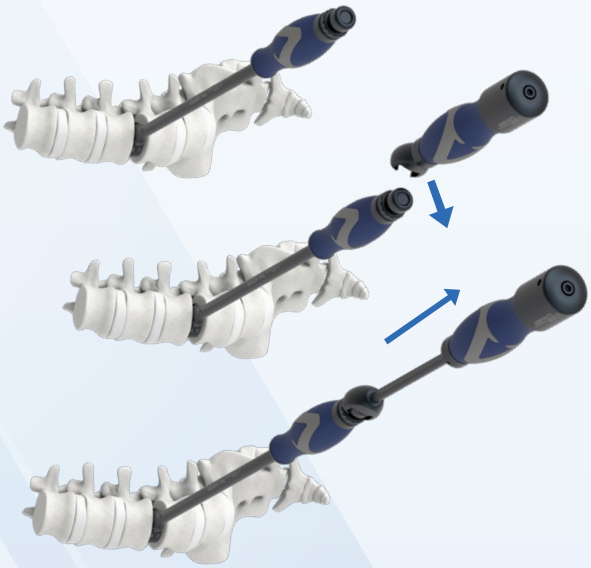
3.7 Utilize the Penfield (KZA050000) and Ball Tip Probe (KZA040000) to verify the boundaries of the discectomy.

4.0 IMPLANT TRIALING ASSEMBLY AND INSERTION

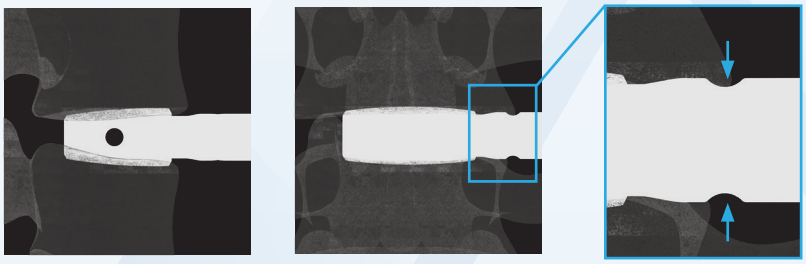
4.1 Implant Trialing

4.1.1 Choose the appropriate footprint Trial (KZF02XXXX). Attach the Trial (KZF02XXXX) to the Trial Inserter (KZB020000) by aligning the pins on the distal end of the Trial Inserter with the holes on the Trial then threading the internal shaft into the Trial until it is secure.

4.1.2 Start with a Trial height less than the disc space height, then increase the Trial height until the desired fit is achieved. The through hole in the Trial and grooves on the Trial Inserter can be used with Fluoroscopy to confirm the desired anatomic alignment.

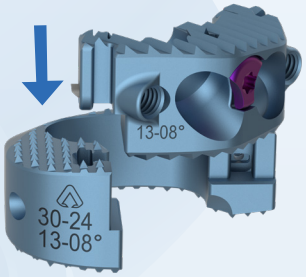


4.1.3 Attach the Slaphammer (KZB120000) to the proximal portion of the Trial Inserter to facilitate removal of the Trials from the disc space.

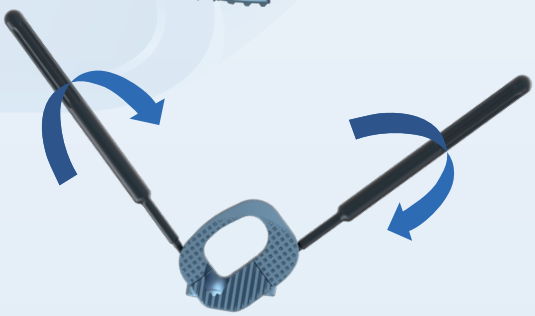


4.2 Implant Assembly

4.2.1 Select the Spacer (KGXXXXXXX, KIXXXXXXX) component that matches the chosen Trial. Select the desired Plate component (KJAXXX00X, KJBXX000X, KJCXX000X, KJDXX000X) which matches the height and lordosis of the chosen Spacer. Attach the plate to the Spacer by aligning the interlocking grooves, then sliding them together until bottomed out. An audible click will confirm that the components have automatically been locked together.



4.2.2 If necessary, the Plate and Spacer may be disassembled by threading two Implant Disassembly Drivers (KZF090000) into the two threaded holes in the Spacer until bottomed out then sliding them apart.



4.3 **Implant Insertion with Screw Fixation**

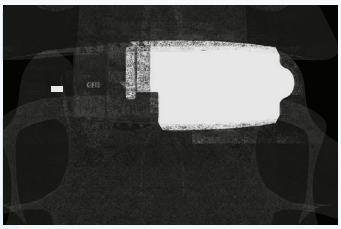
4.3.1 Spacer Insertion

4.3.1.1 Obtain the Spacer Inserter, Screws and Nails (KZF040000), then identify the corresponding Screw Guide (KZF0500XX) that matches the chosen height of the implant height. Attach the Screw Guide to the Spacer Inserter by aligning the arrows, then sliding the two components together until an audible click is heard.

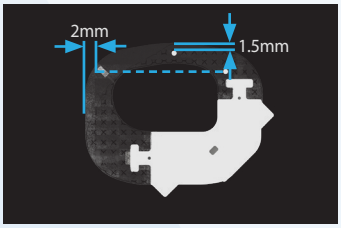
4.3.1.2 Once the Screw Guide is assembled to the Spacer Inserter, align the implant to the inserter and thread the two proximal knobs until the implant is secure.

4.3.1.3 Insert the distal portion of the implant into the disc space, then impact using the Mallet (KZB110000) until the desired depth is achieved. Confirm anatomic alignment using the horizontal/ vertical lasermarkings or grooves on the inserter with fluoroscopy.

4.3.1.4 The Spacer Inserter (KZF030000) may be used in lieu of the Spacer Inserter, Nails and Screws (KZF040000) if Screw insertion without the inserter attached is preferred

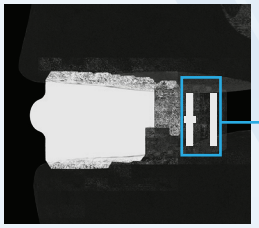


A/P View

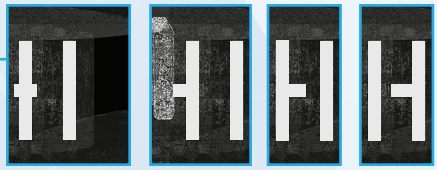


HA PEEK Radiographic Marker Locations

The indicator should be aligned with the patient's coronal and sagittal planes.

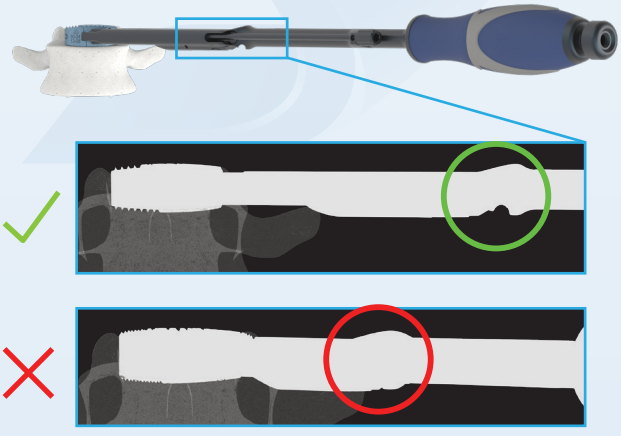


M/L View



Correct Marker Position

Incorrect Marker Positions



4.3.1.5 Screw Preparation

4.3.1.5.1 Straight **(with or without Inserter attached)**

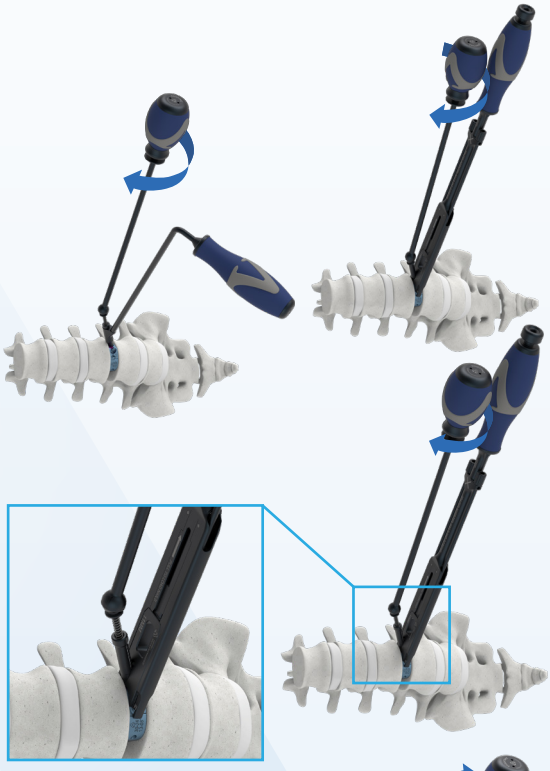
4.3.1.5.1.1 Set the Straight Drill (KZC010010) depth by depressing the locking lever and then rotating the knurled knob until the depth line on the window aligns with the desired depth number.

4.3.1.5.1.2 Attach the Modular Egg Handle (EDDEATAAZ) or Power Driver.

4.3.1.5.1.3 Place the distal end of the Drill into the Screw Guide (KZF0500XX) and advance the Drill until bottomed out (set depth above, mm).

4.3.1.5.1.4 Repeat steps above with the Adjustable Depth Tap (KZC030010) if desired.

4.3.1.5.1.5 Attach the Screw Driver (KZC040000) to the Modular Axial Ratchet Handle (EAECDUBBZ) then attach the Screw by pressing tip of Screw Driver into Screw creating a "Stick Fit" then insert screw into prepared hole.



4.3.1.5.2 Variable Angle **(without Inserter attached)**

4.3.1.5.2.1 Attach the Variable Angle Drill, Short (KZC110010) to the Modular Egg Handle or Power Driver. 4.3.1.5.2.2 Place the Variable Angle Drill, Short into the Variable Angle Drill Guide, Short (KZC100020), then place the Variable Angle Drill Guide Tip into the Spacer screw hole and advance the Variable Angle Drill until bottomed out (15mm).

4.3.1.5.2.3 Repeat the steps above with the Variable Angle Tap, Short (KZC130010) if desired.

4.3.1.5.2.4 Attach the Variable Angle Screwdriver, Short (KZC140010) to the Egg Handle, then attach the Screw by pressing the tip of the Variable Angle Screwdriver into the Screw creating a "Stick Fit", then insert the screw into the prepared hole.

4.3.1.5.3 Variable Angle Self-Centering **(with Inserter Attached)**

4.3.1.5.3.1 Attach the Variable Angle Drill Guided, Long (KZC111020) to the Modular Egg Handle or Power Driver.

4.3.1.5.3.2 Place the Variable Angle Drill Guide Tip into the Screw Guide, then advance the Variable Angle Drill until bottomed out (15mm).

4.3.1.5.3.3 Repeat the steps above with the Variable Angle Tap, Guided, Long (KZC131020) if desired.

4.3.1.5.3.4 Attach the Variable Angle Screwdriver, Short (KZC140010) to the Egg Handle, then attach the Screw by pressing the tip of the Variable Angle Screwdriver into the Screw creating a "Stick Fit", then insert the Screw into the prepared hole.

4.3.1.5.4 Fixed Angle (Drill, Tap, Screw) (with or without Inserter attached)

4.3.1.5.4.1 Connect the Modular Egg Handle or Power Driver to the proximal end of the Fixed Angle Driver (KZC210000). Attach the drill bit (KZC220115) to the distal end of the Fixed Angle Driver by pulling back on the Egg Handle or Power Driver then threading them together.

4.3.1.5.4.2 Place the Drill Bit into the Screw Guide, then advance the Fixed Angle Driver until the Drill Bit is bottomed out (15mm).

4.3.1.5.4.3 Repeat steps above with the Fixed Angle Tap Bit, Long (KZC230150) if desired.

4.3.1.5.4.4 Attach the Screwdriver Bit to the distal end of the Fixed Angle Driver, then connect the Modular Egg Handle to the proximal end. Attach the Screw by pressing the tip of the Screwdriver Bit (KZC140010) into the Screw creating a "Stick Fit", then insert the Screw into the prepared hole.

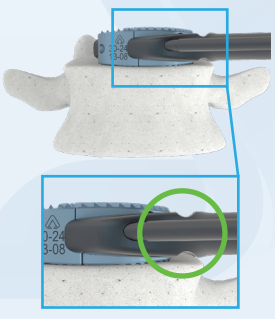
4.3.1.6 Fixed Angle (Awl) (KZC200000) (without Inserter attached)

4.3.1.6.1 Place the distal end in the plate hole. Impact the knob using the Mallet (KZB110000) until the desired depth is achieved. The Slaphammer can be attached to the knob to assist with removing the Awl from the bone.

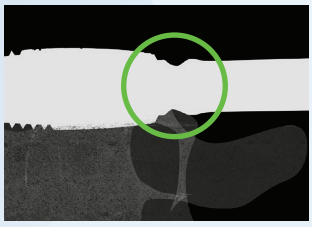
4.3.1.7 Detaching Spacer

4.3.1.7.1 Unthread the proximal knobs of the Spacer Inserter from the Spacer, then remove. If necessary, the Inserter Knob Driver (KZB090000) can be attached to the Modular Axial Ratchet, then inserted into the Inserter Knob to facilitate removal.

The indicator should be aligned with the patient's coronal and sagittal planes.



Inserter groove

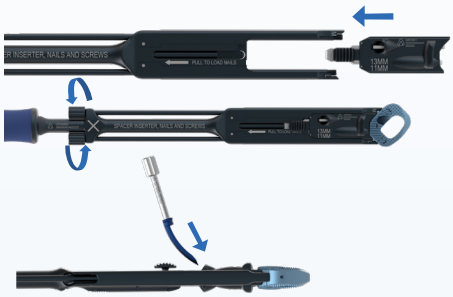


Fluoroscopy View

4.4 **Implant Insertion and Nail Fixation**

4.4.1 Obtain the Implant Inserter, then identify the corresponding Nail Guide (KZF0700XX) that matches the chosen Spacer height. Attach the Nail Guide to the Spacer Inserter by aligning the arrows, then sliding the two components together.

4.4.2 Once the Nail Guide is assembled to the Implant Inserter, align the Implant (KJAXX000X) to the inserter, then thread the lateral knobs until the Implant is secure.



4.4.3 Once the Spacer is attached, pull the slide button back until the button locks into the proximal position. Select appropriate length nails for the attached Spacer by referencing the Nail Length Table. Pull the button back, then insert the Nail (KF00000XX) until the Nail seats flush in each one of the 2 channels. Release the slide button to capture the nails. The Nail Insertion Tools (KZF100000) may be utilized to assist in Nail Assembly.

4.4.4 Insert the distal portion of the Implant into the disc space, then impact using the Mallet (KZB110000) until the desired depth is achieved.

4.4.5 Once the implant is in the desired location within the disc space, thread the Impaction Rod (KZB100000) into the proximal end of the Implant Inserter, then impact the Impaction Rod with the Mallet until bottomed out (42mm).

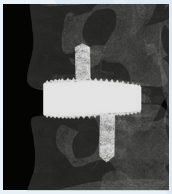
4.4.5.1 Unthread the Implant Inserter from the Spacer, then remove.

4.5 **Fixation Locking**

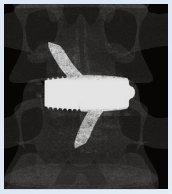
4.5.1 Attach the Lockdriver (KZC050000) to the Modular Ratcheting Axial Handle then insert the tip of the Lockdriver into the Spacer Cam component and rotate 180 degrees.

4.3.1.6 Fixed Angle (Awl) (KZC200000) (without Inserter attached)

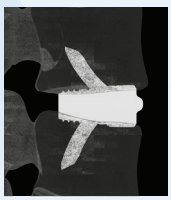
4.3.1.6.1 All cams for all plates in this system lock at 180 degrees of rotation.



Oblique View

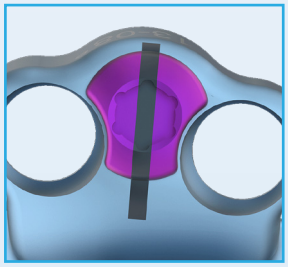


Anterior View

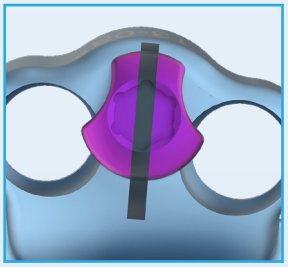


Lateral View

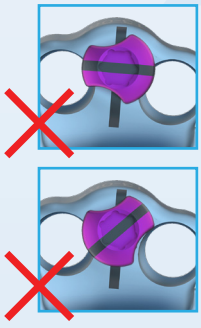
* (Zero Plate and Half Plate Lower Cam (T8) - 180° (KJAXXX00X, KJBXX00X, KJCXX00X)
Full Plate Upper Cam (T20) - 180° (KJDXX00X))



Unlocked Position



Locked Position



4.6 **Implant Removal**

4.6.1 Screw Removal

4.6.1.1 Attach the Lockdriver (KZC050000) to the Modular Ratcheting Axial Handle, then insert the tip of Lockdriver into the Spacer Cam component and rotate 180 degrees to the unlocked position.

4.6.1.2 Attach the Screw Remover (KZC060000) to the screw by aligning the hexalobe feature, then threading the proximal knob clockwise until resistance is felt. Once securely attached, rotate the silicone handle counter-clockwise with upward force until the screw is removed.

4.6.1 Nail Removal

4.6.2.1 Attach the Screw Remover (KZC060000) to the screw by aligning the hexalobe feature, then threading the proximal knob clockwise until resistance is felt. Once securely attached, rotate the silicone handle counter-clockwise with upward force until the screw is removed.

4.6.2.2 Attach the Nail Remover (KZC070000) to the screw by threading the proximal knob clockwise until resistance is felt. Once securely attached, connect the slaphammer (KZB120000) to the Nail Remover and reverse impact in an arched motion until the nail is removed.

4.6 **Implant Removal**

4.6.1 Obtain the Spacer Inserter (KZF040000) then identify the corresponding Screw Guide (KZF0500XX) that matches the chosen Implant height. Attach the Screw Guide to the Spacer Inserter, then slide the two components together.

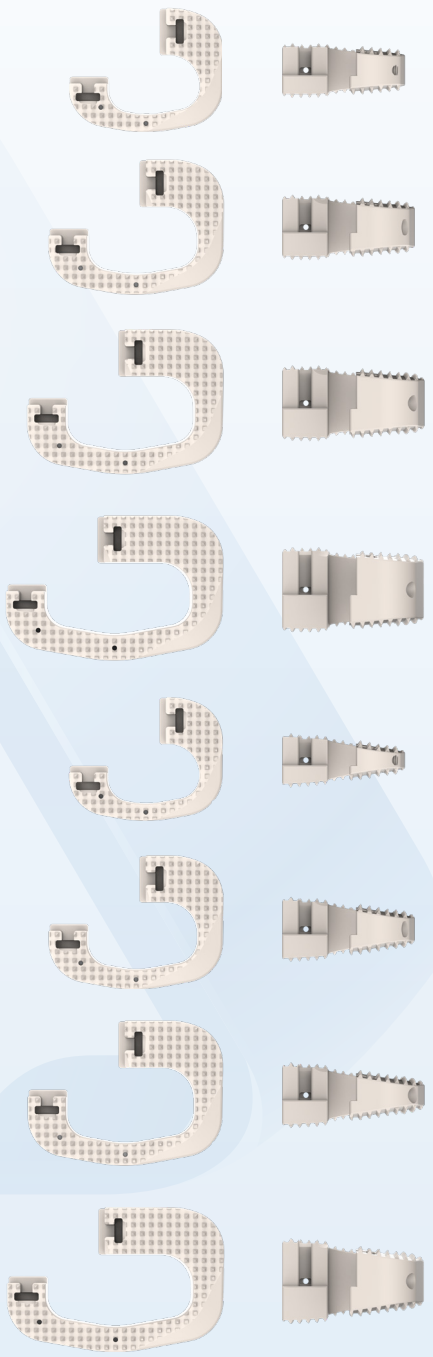
4.7.2 Once the Screw Guide is assembled to the Spacer Inserter, align the Implant to the inserter and thread the proximal knobs until the Implant is secure.

4.7.3 Assemble the Slap Hammer to the Spacer Inserter, then reverse impact until the Spacer is removed.

EL CAPITAN OBLIQUE ALIF HA PEEK OFFERING

OBLIQUE ALIF SPACER, HA PEEK

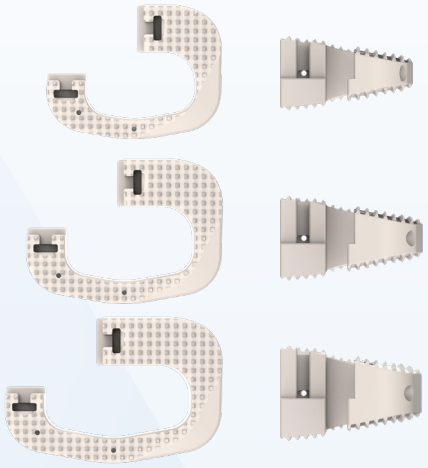
Part Number	Description	Qty
KG302411A	Oblique ALIF Spacer, HA PEEK, 30mm x 24mm x 11mm, 8°, Non-Sterile	2
KG302413A	Oblique ALIF Spacer, HA PEEK, 30mm x 24mm x 13mm, 8°, Non-Sterile	2
KG302415A	Oblique ALIF Spacer, HA PEEK, 30mm x 24mm x 15mm, 8°, Non-Sterile	2
KG302417A	Oblique ALIF Spacer, HA PEEK, 30mm x 24mm x 17mm, 8°, Non-Sterile	2
KG302419A	Oblique ALIF Spacer, HA PEEK, 30mm x 24mm x 19mm, 8°, Non-Sterile	2
KG342611A	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 11mm, 8°, Non-Sterile	2
KG342613A	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 13mm, 8°, Non-Sterile	2
KG342615A	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 15mm, 8°, Non-Sterile	2
KG342617A	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 17mm, 8°, Non-Sterile	2
KG342619A	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 19mm, 8°, Non-Sterile	2
KG382811A	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 11mm, 8°, Non-Sterile	2
KG382813A	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 13mm, 8°, Non-Sterile	2
KG382815A	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 15mm, 8°, Non-Sterile	2
KG382817A	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 17mm, 8°, Non-Sterile	2
KG382819A	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 19mm, 8°, Non-Sterile	2
KG382821A	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 21mm, 8°, Non-Sterile	2
KG422811A	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 11mm, 8°, Non-Sterile	2
KG422813A	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 13mm, 8°, Non-Sterile	2
KG422815A	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 15mm, 8°, Non-Sterile	2
KG422817A	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 17mm, 8°, Non-Sterile	2
KG422819A	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 19mm, 8°, Non-Sterile	2
KG422821A	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 21mm, 8°, Non-Sterile	2
KG302411B	Oblique ALIF Spacer, HA PEEK, 30mm x 24mm x 11mm, 15°, Non-Sterile	2
KG302413B	Oblique ALIF Spacer, HA PEEK, 30mm x 24mm x 13mm, 15°, Non-Sterile	2
KG302415B	Oblique ALIF Spacer, HA PEEK, 30mm x 24mm x 15mm, 15°, Non-Sterile	2
KG302417B	Oblique ALIF Spacer, HA PEEK, 30mm x 24mm x 17mm, 15°, Non-Sterile	2
KG302419B	Oblique ALIF Spacer, HA PEEK, 30mm x 24mm x 19mm, 15°, Non-Sterile	2
KG342611B	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 11mm, 15°, Non-Sterile	2
KG342613B	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 13mm, 15°, Non-Sterile	2
KG342615B	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 15mm, 15°, Non-Sterile	2
KG342617B	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 17mm, 15°, Non-Sterile	2
KG342619B	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 19mm, 15°, Non-Sterile	2
KG382811B	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 11mm, 15°, Non-Sterile	2
KG382813B	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 13mm, 15°, Non-Sterile	2
KG382815B	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 15mm, 15°, Non-Sterile	2
KG382817B	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 17mm, 15°, Non-Sterile	2
KG382819B	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 19mm, 15°, Non-Sterile	2
KG382821B	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 21mm, 15°, Non-Sterile	2
KG422811B	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 11mm, 15°, Non-Sterile	2
KG422813B	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 13mm, 15°, Non-Sterile	2
KG422815B	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 15mm, 15°, Non-Sterile	2
KG422817B	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 17mm, 15°, Non-Sterile	2
KG422819B	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 19mm, 15°, Non-Sterile	2
KG422821B	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 21mm, 15°, Non-Sterile	2



EL CAPITAN OBLIQUE ALIF HA PEEK OFFERING

ALIF SPACER, HA PEEK

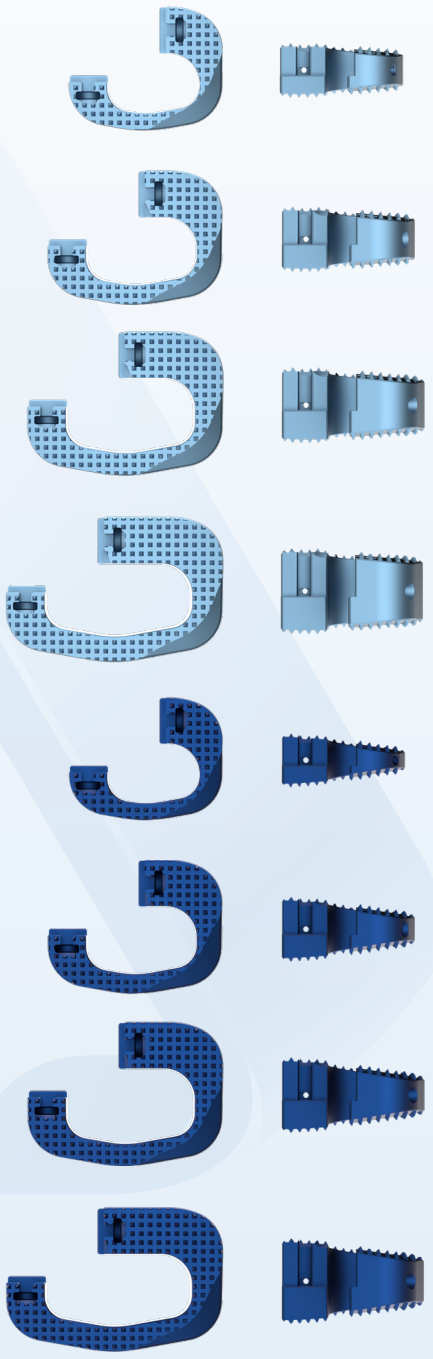
Part Number	Description	Qty
KG342615C	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 15mm, 20°, Non-Sterile	2
KG342617C	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 17mm, 20°, Non-Sterile	2
KG342619C	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 19mm, 20°, Non-Sterile	2
KG342621C	Oblique ALIF Spacer, HA PEEK, 34mm x 26mm x 19mm, 20°, Non-Sterile	2
KG382815C	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 15mm, 20°, Non-Sterile	2
KG382817C	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 17mm, 20°, Non-Sterile	2
KG382819C	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 19mm, 20°, Non-Sterile	2
KG382821C	Oblique ALIF Spacer, HA PEEK, 38mm x 28mm x 21mm, 20°, Non-Sterile	2
KG422815C	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 15mm, 20°, Non-Sterile	2
KG422817C	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 17mm,20°, Non-Sterile	2
KG422819C	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 19mm, 20°, Non-Sterile	2
KG422821C	Oblique ALIF Spacer, HA PEEK, 42mm x 28mm x 21mm, 20°, Non-Sterile	2



EL CAPITAN OBLIQUE ALIF SPIKED TITANIUM OFFERING

OBLIQUE ALIF SPACER, SPIKED TITANIUM

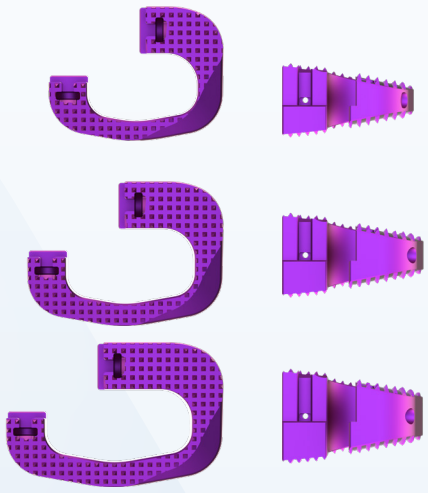
Part Number	Description	Qty
KI302411A	Oblique ALIF Spacer, Spiked Titanium, 30mm x 24mm x 11mm, 8°, Non-Sterile	2
KI302413A	Oblique ALIF Spacer, Spiked Titanium, 30mm x 24mm x 13mm, 8°, Non-Sterile	2
KI302415A	Oblique ALIF Spacer, Spiked Titanium, 30mm x 24mm x 15mm, 8°, Non-Sterile	2
KI302417A	Oblique ALIF Spacer, Spiked Titanium, 30mm x 24mm x 17mm, 8°, Non-Sterile	2
KI302419A	Oblique ALIF Spacer, Spiked Titanium, 30mm x 24mm x 19mm, 8°, Non-Sterile	2
KI342611A	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 11mm, 8°, Non-Sterile	2
KI342613A	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 13mm, 8°, Non-Sterile	2
KI342615A	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 15mm, 8°, Non-Sterile	2
KI342617A	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 17mm, 8°, Non-Sterile	2
KI342619A	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 19mm, 8°, Non-Sterile	2
KI382811A	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 11mm, 8°, Non-Sterile	2
KI382813A	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 13mm, 8°, Non-Sterile	2
KI382815A	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 15mm, 8°, Non-Sterile	2
KI382817A	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 17mm, 8°, Non-Sterile	2
KI382819A	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 19mm, 8°, Non-Sterile	2
KI382821A	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 21mm, 8°, Non-Sterile	2
KI422811A	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 11mm, 8°, Non-Sterile	2
KI422813A	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 13mm, 8°, Non-Sterile	2
KI422815A	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 15mm, 8°, Non-Sterile	2
KI422817A	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 17mm, 8°, Non-Sterile	2
KI422819A	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 19mm, 8°, Non-Sterile	2
KI422821A	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 21mm, 8°, Non-Sterile	2
KI302411B	Oblique ALIF Spacer, Spiked Titanium, 30mm x 24mm x 11mm, 15°, Non-Sterile	2
KI302413B	Oblique ALIF Spacer, Spiked Titanium, 30mm x 24mm x 13mm, 15°, Non-Sterile	2
KI302415B	Oblique ALIF Spacer, Spiked Titanium, 30mm x 24mm x 15mm, 15°, Non-Sterile	2
KI302417B	Oblique ALIF Spacer, Spiked Titanium, 30mm x 24mm x 17mm, 15°, Non-Sterile	2
KI302419B	Oblique ALIF Spacer, Spiked Titanium, 30mm x 24mm x 19mm, 15°, Non-Sterile	2
KI342611B	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 11mm, 15°, Non-Sterile	2
KI342613B	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 13mm, 15°, Non-Sterile	2
KI342615B	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 15mm, 15°, Non-Sterile	2
KI342617B	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 17mm, 15°, Non-Sterile	2
KI342619B	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 19mm, 15°, Non-Sterile	2
KI382811B	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 11mm, 15°, Non-Sterile	2
KI382813B	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 13mm, 15°, Non-Sterile	2
KI382815B	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 15mm, 15°, Non-Sterile	2
KI382817B	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 17mm, 15°, Non-Sterile	2
KI382819B	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 19mm, 15°, Non-Sterile	2
KI382821B	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 21mm, 15°, Non-Sterile	2
KI422811B	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 11mm, 15°, Non-Sterile	2
KI422813B	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 13mm, 15°, Non-Sterile	2
KI422815B	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 15mm, 15°, Non-Sterile	2
KI422817B	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 17mm, 15°, Non-Sterile	2
KI422819B	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 19mm, 15°, Non-Sterile	2
KI422821B	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 21mm, 15°, Non-Sterile	2



EL CAPITAN OBLIQUE ALIF SPIKED TITANIUM OFFERING

OBLIQUE ALIF SPACER, SPIKED TITANIUM

Part Number	Description	Qty
KI342615C	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 15mm, 20°, Non-Sterile	2
KI342617C	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 17mm, 20°, Non-Sterile	2
KI342619C	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 19mm, 20°, Non-Sterile	2
KI342621C	Oblique ALIF Spacer, Spiked Titanium, 34mm x 26mm x 21mm, 20°, Non-Sterile	2
KI382815C	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 15mm, 20°, Non-Sterile	2
KI382817C	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 17mm, 20°, Non-Sterile	2
KI382819C	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 19mm, 20°, Non-Sterile	2
KI382821C	Oblique ALIF Spacer, Spiked Titanium, 38mm x 28mm x 21mm, 20°, Non-Sterile	2
KI422815C	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 15mm, 20°, Non-Sterile	2
KI422817C	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 17mm, 20°, Non-Sterile	2
KI422819C	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 19mm, 20°, Non-Sterile	2
KI422821C	Oblique ALIF Spacer, Spiked Titanium, 42mm x 28mm x 21mm, 20°, Non-Sterile	2



EL CAPITAN OBLIQUE ALIF PLATE OFFERING

OBLIQUE ALIF ZERO PLATE, 8°

Part Number	Description	Qty
KJA11000A	Oblique ALIF Zero Plate, 11mm, 8°	2
KJA13000A	Oblique ALIF Zero Plate, 13mm, 8°	2
KJA15000A	Oblique ALIF Zero Plate, 15mm, 8°	2
KJA17000A	Oblique ALIF Zero Plate, 17mm, 8°	2
KJA19000A	Oblique ALIF Zero Plate, 19mm, 8°	1
KJA21000A	Oblique ALIF Zero Plate, 21mm, 8°	1

OBLIQUE ALIF ZERO PLATE, 15°

Part Number	Description	Qty
KJA11000B	Oblique ALIF Zero Plate, 11mm, 15°	2
KJA13000B	Oblique ALIF Zero Plate, 13mm, 15°	2
KJA15000B	Oblique ALIF Zero Plate, 15mm, 15°	2
KJA17000B	Oblique ALIF Zero Plate, 17mm, 15°	2
KJA19000B	Oblique ALIF Zero Plate, 19mm, 15°	1
KJA21000B	Oblique ALIF Zero Plate, 21mm, 15°	1

OBLIQUE ALIF ZERO PLATE, 20°

Part Number	Description	Qty
KJA15000C	Oblique ALIF Zero Plate, 15mm, 20°	2
KJA17000C	Oblique ALIF Zero Plate, 17mm, 20°	2
KJA19000C	Oblique ALIF Zero Plate, 19mm, 20°	1
KJA21000C	Oblique ALIF Zero Plate, 21mm, 20°	1

OBLIQUE ALIF LS-RI HALF PLATE, 8°

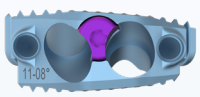
Part Number	Description	Qty
KJB11000A	Oblique ALIF LS-RI Half Plate, 11mm, 8°	1
KJB13000A	Oblique ALIF LS-RI Half Plate, 13mm, 8°	1
KJB15000A	Oblique ALIF LS-RI Half Plate, 15mm, 8°	1
KJB17000A	Oblique ALIF LS-RI Half Plate, 17mm, 8°	1
KJB19000A	Oblique ALIF LS-RI Half Plate, 19mm, 8°	1
KJB21000A	Oblique ALIF LS-RI Half Plate, 21mm, 8°	1

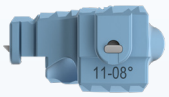
OBLIQUE ALIF LS-RI HALF PLATE, 15°

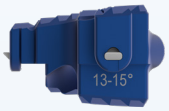
Part Number	Description	Qty
KJB11000B	Oblique ALIF LS-RI Half Plate, 11mm, 15°	1
KJB13000B	Oblique ALIF LS-RI Half Plate, 13mm, 15°	1
KJB15000B	Oblique ALIF LS-RI Half Plate, 15mm, 15°	1
KJB17000B	Oblique ALIF LS-RI Half Plate, 17mm, 15°	1
KJB19000B	Oblique ALIF LS-RI Half Plate, 19mm, 15°	1
KJB21000B	Oblique ALIF LS-RI Half Plate, 21mm, 15°	1

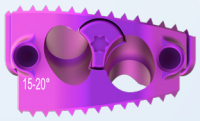
OBLIQUE ALIF LS-RI HALF PLATE, 20°

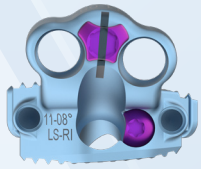
Part Number	Description	Qty
KJB15000C	Oblique ALIF LS-RI Half Plate, 15mm, 20°	1
KJB17000C	Oblique ALIF LS-RI Half Plate, 17mm, 20°	1
KJB19000C	Oblique ALIF LS-RI Half Plate, 19mm, 20°	1
KJB21000C	Oblique ALIF LS-RI Half Plate, 21mm, 20°	1

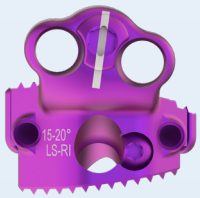












EL CAPITAN OBLIQUE ALIF PLATE OFFERING

OBLIQUE ALIF LI-RS HALF PLATE, 8°

Part Number	Description	Qty
KJC11000A	Oblique ALIF LI-RS Half Plate, 11mm, 8°	1
KJC13000A	Oblique ALIF LI-RS Half Plate, 13mm, 8°	1
KJC15000A	Oblique ALIF LI-RS Half Plate, 15mm, 8°	1
KJC17000A	Oblique ALIF LI-RS Half Plate, 17mm, 8°	1
KJC19000A	Oblique ALIF LI-RS Half Plate, 19mm, 8°	1
KJC21000A	Oblique ALIF LI-RS Half Plate, 21mm, 8°	1

OBLIQUE ALIF LI-RS HALF PLATE, 15°

Part Number	Description	Qty
KJC11000B	Oblique ALIF LI-RS Half Plate, 11mm, 15°	1
KJC13000B	Oblique ALIF LI-RS Half Plate, 13mm, 15°	1
KJC15000B	Oblique ALIF LI-RS Half Plate, 15mm, 15°	1
KJC17000B	Oblique ALIF LI-RS Half Plate, 17mm, 15°	1
KJC19000B	Oblique ALIF LI-RS Half Plate, 19mm, 15°	1
KJC21000B	Oblique ALIF LI-RS Half Plate, 21mm, 15°	1

OBLIQUE ALIF LI-RS HALF PLATE, 20°

Part Number	Description	Qty
KJC15000C	Oblique ALIF LI-RS Half Plate, 15mm, 20°	1
KJC17000C	Oblique ALIF LI-RS Half Plate, 17mm, 20°	1
KJC19000C	Oblique ALIF LI-RS Half Plate, 19mm, 20°	1
KJC21000C	Oblique ALIF LI-RS Half Plate, 21mm, 20°	1

OBLIQUE ALIF FULL PLATE, 8°

Part Number	Description	Qty
KJD11000A	Oblique ALIF Full Plate, 11mm, 8°	1
KJD13000A	Oblique ALIF Full Plate, 13mm, 8°	1
KJD15000A	Oblique ALIF Full Plate, 15mm, 8°	1
KJD17000A	Oblique ALIF Full Plate, 17mm, 8°	1
KJD19000A	Oblique ALIF Full Plate, 19mm, 8°	1
KJD21000A	Oblique ALIF Full Plate, 21mm, 8°	1

OBLIQUE ALIF FULL PLATE, 15°

Part Number	Description	Qty
KJD11000B	Oblique ALIF Full Plate, 11mm, 15°	1
KJD13000B	Oblique ALIF Full Plate, 13mm, 15°	1
KJD15000B	Oblique ALIF Full Plate, 15mm, 15°	1
KJD17000B	Oblique ALIF Full Plate, 17mm, 15°	1
KJD19000B	Oblique ALIF Full Plate, 19mm, 15°	1
KJD21000B	Oblique ALIF Full Plate, 21mm, 15°	1

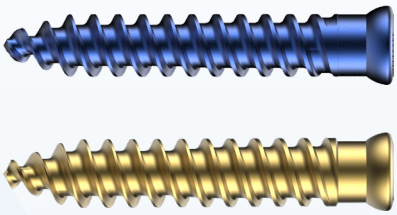
OBLIQUE ALIF FULL PLATE, 20°

Part Number	Description	Qty
KJD15000C	Oblique ALIF Full Plate, 15mm, 20°	1
KJD17000C	Oblique ALIF Full Plate, 17mm, 20°	1
KJD19000C	Oblique ALIF Full Plate, 19mm, 20°	1
KJD21000C	Oblique ALIF Full Plate, 21mm, 20°	1

EL CAPITAN OBLIQUE ALIF PLATE SCREWS AND NAILS OFFERING

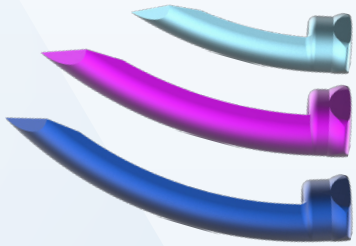
ALIF SCREWS, SELF-DRILLING, VARIABLE

Part Number	Description	Qty
KEAB50020	ALIF Screws, Self-Drilling, Variable, 5.0mm x 20mm	8
KEAB50025	ALIF Screws, Self-Drilling, Variable, 5.0mm x 25mm	8
KEAB50030	ALIF Screws, Self-Drilling, Variable, 5.0mm x 30mm	8
KEAB55020	ALIF Screws, Self-Drilling, Variable, 5.5mm x 20mm	8
KEAB55025	ALIF Screws, Self-Drilling, Variable, 5.5mm x 25mm	8
KEAB55030	ALIF Screws, Self-Drilling, Variable, 5.5mm x 30mm	8



ALIF NAILS

Part Number	Description	Qty
KF0000020	ALIF Nail, 5.5mm x 20mm	8
KF0000025	ALIF Nail, 5.5mm x 25mm	8
KF0000030	ALIF Nail, 5.5mm x 30mm	8



EL CAPITAN OBLIQUE ALIF INSTRUMENT OFFERING

Part Number	Description	Qty
KZA010000	Midline Marker	3
KZA020010	Annulotomy Guide, Small	1
KZA020020	Annulotomy Guide, Medium	1
KZA020030	Annulotomy Guide, Large	1
KZA020040	Annulotomy Guide, X-Large	1
KZA030000	Annulotomy Knife, Straight	1
KZA040000	Ball Tip Probe, 90°	1
KZA050000	Penfield, #4	1
KZA060000	Lexcel Rongeur, Serrated	1
KZA09SQ04	Pituitary, Straight #4, Serrated	1
KZA09SQ06	Pituitary, Straight #6, Serrated	1
KZA10SZ04	Kerrison #4	1
KZA10SZ06	Kerrison #6	1
KZA11SZ18	Osteotome, Straight, 18mm	OPT
KZA11SZ30	Osteotome, Straight, 30mm	OPT
KZA12SZ18	Cobb, Straight, 18mm	1
KZA12SZ30	Cobb, Straight, 30mm	1
KZA13SR18	Endplate Rasp, Double Sided, Straight, 18mm	1
KZA13SR24	Endplate Rasp, Double Sided, Straight, 24mm	1
KZA1900007	Disc Distractor, 7mm	1
KZA1900009	Disc Distractor, 9mm	1

EL CAPITAN OBLIQUE ALIF INSTRUMENT OFFERING

Part Number	Description	Qty
KZA14SQ04	Cup Curette, Straight, #4 With Teeth	
KZA14SQ06	Cup Curette, Straight #6 With Teeth	
KZA14SP04	Cup Curette, Up, 30° #4 With Teeth	
KZA14SP06	Cup Curette, Up, 30° #6 With Teeth	
KZA14SY04	Cup Curette, Up, 90° #4 With Teeth	
KZA14SY06	Cup Curette, Up, 90° #6 With Teeth	
KZA14ST04	Cup Curette, Down, 30° #4 With Teeth	
KZA14ST06	Cup Curette, Down, 30° #6 With Teeth	
KZA14SV04	Cup Curette, Down 90°, #4 With Teeth	
KZA14SV06	Cup Curette, Down 90°, #6, With Teeth	
KZA15SZ04	Uterine Curette, Straight, #4	
KZA15SZ06	Uterine Curette, Straight, #6	
KZA16SZ06	Stirrup Curette, Straight, #6	
KZA16SZ08	Stirrup Curette, Straight, #8	
KZA170000	Modular Rotating Distractor Handle	1
KZA180011	Modular Rotating Distractor, 11mm	1
KZA180013	Modular Rotating Distractor, 13mm	1
KZA180015	Modular Rotating Distractor, 15mm	1
KZA180017	Modular Rotating Distractor, 17mm	1
KZA180019	Modular Rotating Distractor, 19mm	1
KZA180021	Modular Rotating Distractor, 21mm	1

EL CAPITAN OBLIQUE ALIF SPACER INSTRUMENTS

Part Number	Description	Qty
KZF010000	Trial Inserter	2
KZF030000	Spacer Inserter	1
KZF040000	Spacer Inserter, Nails and Screws	1
KZF050011	Screw Guide, Zero Plate, 11mm	1
KZF050015	Screw Guide, Zero Plate,15mm	1
KZF050017	Screw Guide, Zero Plate,17mm	1
KZF050019	Screw Guide, Zero Plate,19mm	1
KZF050021	Screw Guide, Zero Plate, 21mm	1
KZF060011	Screw Guide, Half and Full Plate, 11mm	1
KZF060013	Screw Guide, Half and Full Plate, 13mm	1
KZF060015	Screw Guide, Half and Full Plate, 15mm	1
KZF060017	Screw Guide, Half and Full Plate, 17mm	1
KZF060019	Screw Guide, Half and Full Plate, 19mm	1
KZF060021	Screw Guide, Half and Full Plate, 21mm	1
KZF070011	Nail Guide, 11mm	1
KZF070015	Nail Guide, 15mm	1
KZF070017	Nail Guide, 17mm	1
KZF070019	Nail Guide, 19mm	1
KZF070021	Nail Guide, 21mm	1
KZF080000	Straight Tamp	1
KZF090000	Spacer Disassembly Driver	1
KZF100000	Nail Insertion Tool	2
KZB090000	Inserter Knob Driver	1
KZB100000	Nail Impactor	1
KZB110000	Mallet	1
KZB120000	Slaphammer	1

EL CAPITAN OBLIQUE ALIF TRIALS

OBLIQUE ALIF TRIAL, SMALL, 8°

Part Number	Description	Qty
KZF02A11A	Oblique ALIF Trial, Small, 11mm, 8°	1
KZF02A13A	Oblique ALIF Trial, Small, 13mm, 8°	1
KZF02A15A	Oblique ALIF Trial, Small, 15mm, 8°	1
KZF02A17A	Oblique ALIF Trial, Small, 17mm, 8°	1
KZF02A19A	Oblique ALIF Trial, Small, 19mm, 8°	1
KZF02A21A	Oblique ALIF Trial, Small, 21mm, 8°	1

OBLIQUE ALIF TRIAL, MEDIUM, 8°

Part Number	Description	Qty
KZF02B11A	Oblique ALIF Trial, Medium, 11mm, 8°	1
KZF02B13A	Oblique ALIF Trial, Medium, 13mm, 8°	1
KZF02B15A	Oblique ALIF Trial, Medium, 15mm, 8°	1
KZF02B17A	Oblique ALIF Trial, Medium, 17mm, 8°	1
KZF02B19A	Oblique ALIF Trial, Medium, 19mm, 8°	1
KZF02B21A	Oblique ALIF Trial, Medium, 21mm, 8°	1

OBLIQUE ALIF TRIAL, LARGE, 8°

Part Number	Description	Qty
KZF02C11A	Oblique ALIF Trial, Large, 11mm, 8°	1
KZF02C13A	Oblique ALIF Trial, Large, 13mm, 8°	1
KZF02C15A	Oblique ALIF Trial, Large, 15mm, 8°	1
KZF02C17A	Oblique ALIF Trial, Large, 17mm, 8°	1
KZF02C19A	Oblique ALIF Trial, Large, 19mm, 8°	1
KZF02C21A	Oblique ALIF Trial, Large, 21mm, 8°	1

OBLIQUE ALIF TRIAL, X-LARGE, 8°

Part Number	Description	Qty
KZF02D11A	Oblique ALIF Trial, X-Large, 11mm, 8°	1
KZF02D13A	Oblique ALIF Trial, X-Large, 13mm, 8°	1
KZF02D15A	Oblique ALIF Trial, X-Large, 15mm, 8°	1
KZF02D17A	Oblique ALIF Trial, X-Large, 17mm, 8°	1
KZF02D19A	Oblique ALIF Trial, X-Large, 19mm, 8°	1
KZF02D21A	Oblique ALIF Trial, X-Large, 21mm, 8°	1

OBLIQUE ALIF TRIAL, SMALL, 15°

Part Number	Description	Qty
KZF02A11B	Oblique ALIF Trial, Small, 11mm, 15°	1
KZF02A13B	Oblique ALIF Trial, Small, 13mm, 15°	1
KZF02A15B	Oblique ALIF Trial, Small, 15mm, 15°	1
KZF02A17B	Oblique ALIF Trial, Small, 17mm, 15°	1
KZF02A19B	Oblique ALIF Trial, Small, 19mm, 15°	1
KZF02A21B	Oblique ALIF Trial, Small, 21mm, 15°	1

OBLIQUE ALIF TRIAL, MEDIUM, 15°

Part Number	Description	Qty
KZF02B11B	Oblique ALIF Trial, Medium, 11mm, 15°	1
KZF02B13B	Oblique ALIF Trial, Medium, 13mm, 15°	1
KZF02B15B	Oblique ALIF Trial, Medium, 15mm, 15°	1
KZF02B17B	Oblique ALIF Trial, Medium, 17mm, 15°	1
KZF02B19B	Oblique ALIF Trial, Medium, 19mm, 15°	1
KZF02B21B	Oblique ALIF Trial, Medium, 21mm, 15°	1

EL CAPITAN OBLIQUE ALIF TRIALS

OBLIQUE ALIF TRIAL, LARGE, 15°

Part Number	Description	Qty
KZF02C11B	Oblique ALIF Trial, Large, 11mm, 15°	1
KZF02C13B	Oblique ALIF Trial, Large, 13mm, 15°	1
KZF02C15B	Oblique ALIF Trial, Large, 15mm, 15°	1
KZF02C17B	Oblique ALIF Trial, Large, 17mm, 15°	1
KZF02C19B	Oblique ALIF Trial, Large, 19mm, 15°	1
KZF02C21B	Oblique ALIF Trial, Large, 21mm, 15°	1

OBLIQUE ALIF TRIAL, X-LARGE, 15°

Part Number	Description	Qty
KZF02D11B	Oblique ALIF Trial, X-Large, 11mm, 15°	1
KZF02D13B	Oblique ALIF Trial, X-Large, 13mm, 15°	1
KZF02D15B	Oblique ALIF Trial, X-Large, 15mm, 15°	1
KZF02D17B	Oblique ALIF Trial, X-Large, 17mm, 15°	1
KZF02D19B	Oblique ALIF Trial, X-Large, 19mm, 15°	1
KZF02D21B	Oblique ALIF Trial, X-Large, 21mm, 15°	1

OBLIQUE ALIF TRIAL, MEDIUM, 20°

Part Number	Description	Qty
KZF02B15C	Oblique ALIF Trial, Medium, 15mm, 20°	1
KZF02B17C	Oblique ALIF Trial, Medium, 17mm, 20°	1
KZF02B19C	Oblique ALIF Trial, Medium, 19mm, 20°	1
KZF02B21C	Oblique ALIF Trial, Medium, 21mm, 20°	1

OBLIQUE ALIF TRIAL, LARGE, 20°

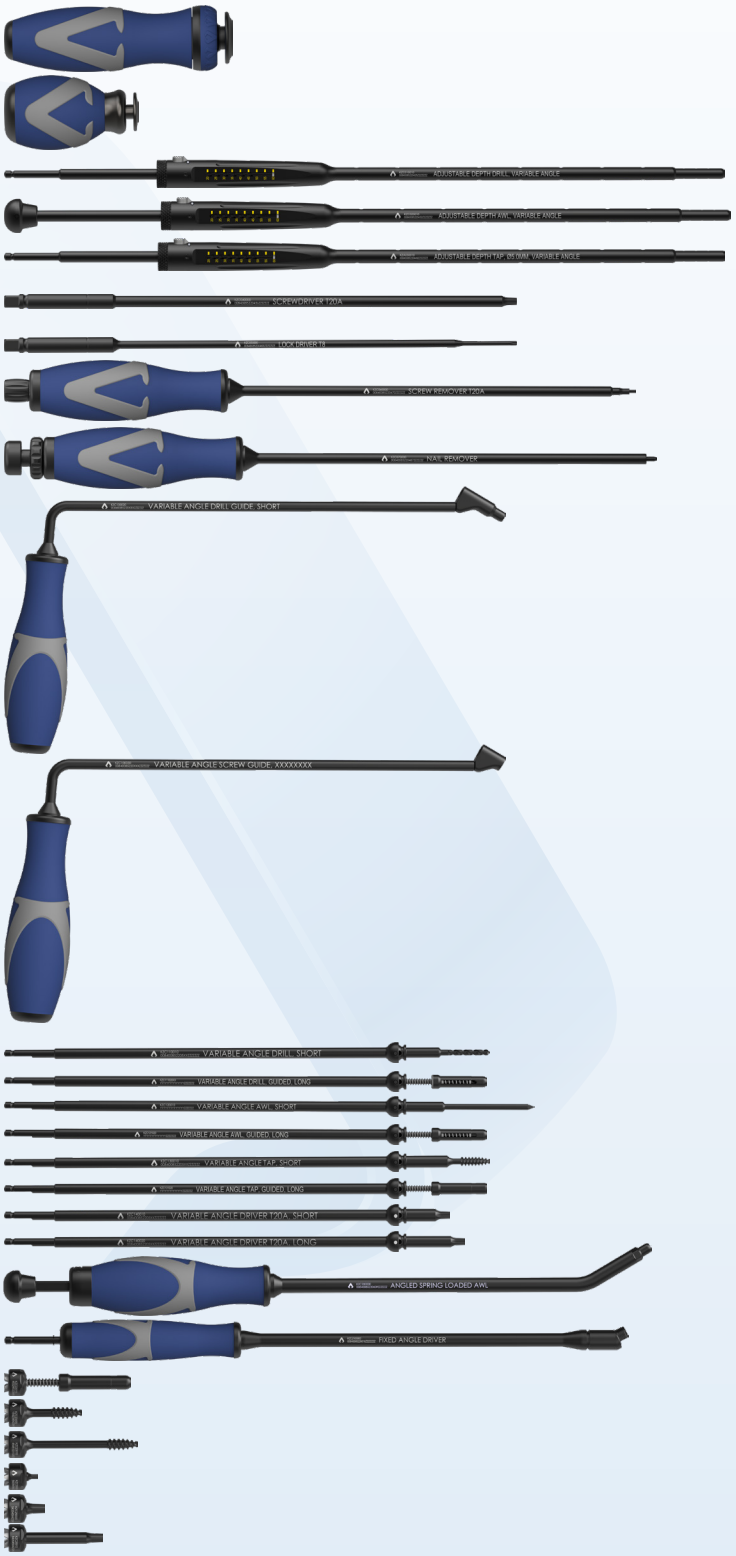
Part Number	Description	Qty
KZF02C15C	Oblique ALIF Trial, Large, 15mm, 20°	1
KZF02C17C	Oblique ALIF Trial, Large, 17mm, 20°	1
KZF02C19C	Oblique ALIF Trial, Large, 19mm, 20°	1
KZF02C21C	Oblique ALIF Trial, Large, 21mm, 20°	1

OBLIQUE ALIF TRIAL, X-LARGE, 20°

Part Number	Description	Qty
KZF02D15C	Oblique ALIF Trial, X-Large, 15mm, 20°	1
KZF02D17C	Oblique ALIF Trial, X-Large, 17mm, 20°	1
KZF02D19C	Oblique ALIF Trial, X-Large, 19mm, 20°	1
KZF02D21C	Oblique ALIF Trial, X-Large, 21mm, 20°	1

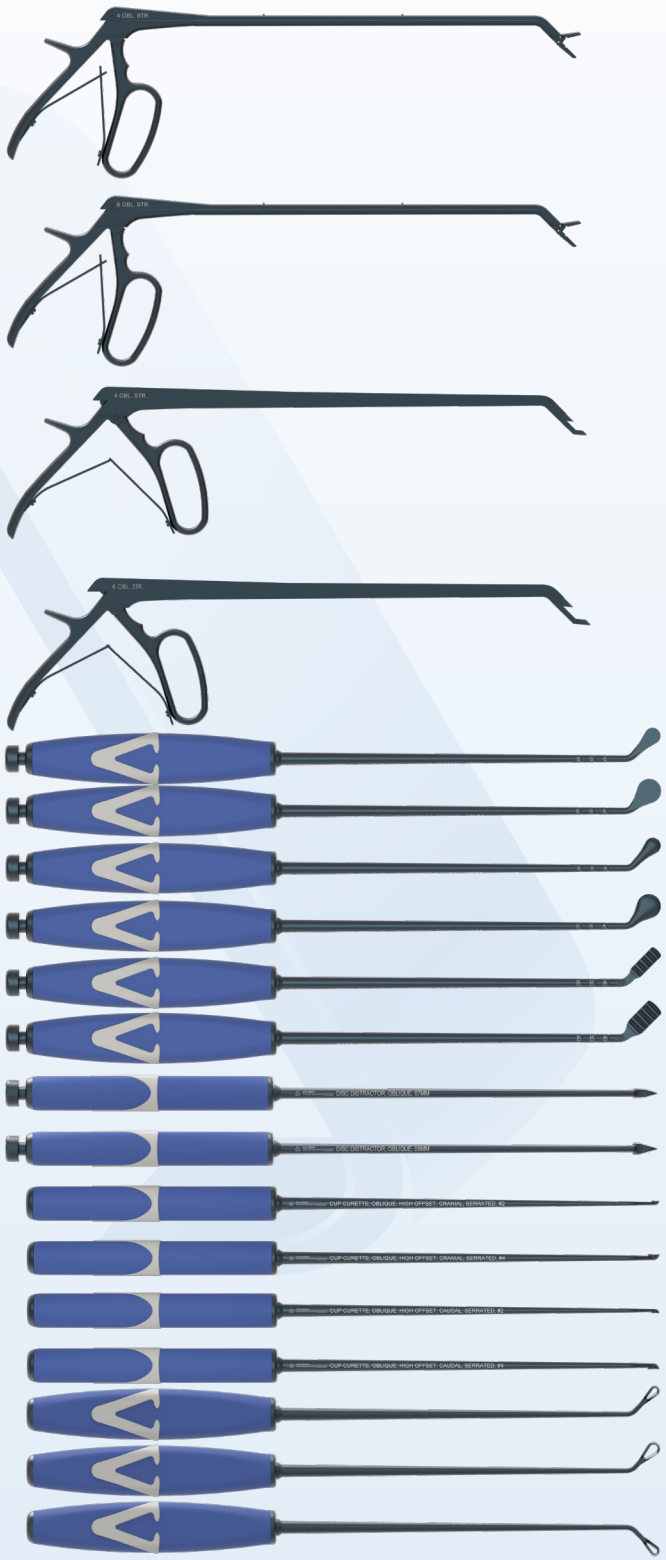
EL CAPITAN OBLIQUE ALIF FIXATION INSTRUMENTS

Part Number	Description	Qty
EAECDUBBZ	Axial, Large, 1/4" Square Ratchet	2
EDDEATAAZ	Egg Handle, AO	2
KZC010010	Adjustable Depth Drill	1
KZC020010	Adjustable Depth Awl	1
KZC030010	Adjustable Depth Tap, Ø5.0mm	1
KZC040000	Screwdriver, T20a	2
KZC050000	Lock Driver, T8	2
KZC060000	Screw Remover, T20a	1
KZC070000	Nail Remover	1
KZC100020	Variable Angle Drill Guide, Short	1
KZC100030	Variable Angle Screw Guide	1
KZC110010	Variable Angle Drill, 20mm	1
KZC111020	Variable Angle Drill, Guided, 15mm	1
KZC120010	Variable Angle Awl, 20mm	1
KZC121020	Variable Angle Awl, Guided, 15mm	1
KZC130010	Variable Angle Tap, 20mm	1
KZC131020	Variable Angle Tap, Guided, 15mm	1
KZC140010	Variable Angle Screwdriver T20a, Short	1
KZC140020	Variable Angle Screwdriver T20a, Long	1
KZC200000	Angled Spring Loaded Awl, 20mm	1
KZC210000	Fixed Angle Driver	2
KZC220115	Fixed Angle Drill Bit, Long, 15mm	2
KZC230050	Fixed Angle Tap Bit, Short Ø5.0mm	1
KZC230150	Fixed Angle Tap Bit, Long, Ø5.0mm	1
KZC250008	Fixed Angle Lockdriver Bit, T8, Short	2
KZC250020	Fixed Angle Screwdriver Bit, T20a, Short	2
KZC250120	Fixed Angle Screwdriver Bit, T20a, Long	2



EL CAPITAN OBLIQUE ALIF ANGLED INSTRUMENTS

Part Number	Description	Qty
KZA09BQ04	Pituitary, Oblique, Straight #4	1
KZA09BQ06	Pituitary, Oblique, Straight #6	1
KZA10BQ04	Kerrison, Oblique, Straight #4	1
KZA10BQ06	Kerrison, Oblique, Straight #6	1
KZA12BE12	Cobb, Oblique, Straight, High Offset Cranial, 12mm	1
KZA12BE18	Cobb, Oblique, Straight, High Offset Cranial, 18mm	1
KZA12BE18	Cobb, Oblique, Straight, High Offset Caudal, 12mm	1
KZA12BE18	Cobb, Oblique, Straight, High Offset Caudal, 18mm	1
KZA13BY10	Rasp, Oblique, Straight, Double Serrated, 10mm	1
KZA13BY14	Rasp, Oblique, Straight, Double Serrated, 14mm	1
KZA19B007	Disc Distractor, Oblique, 7mm	1
KZA19B009	Disc Distractor, Oblique, 9mm	1
KZA14BM02	Cup Curette, Oblique, High Offset Cranial, Serrated, #2	1
KZA14BM04	Cup Curette, Oblique, High Offset Cranial, Serrated, #4	1
KZA14BN02	Cup Curette, Oblique, High Offset Caudal, Serrated, #2	1
KZA14BN04	Cup Curette, Oblique, High Offset Caudal, Serrated, #4	1
KZA15BE02	Uterine Curette, Oblique, High Offset Cranial, #2	1
KZA15BE04	Uterine Curette, Oblique, High Offset Cranial, #4	1
KZA15BF02	Uterine Curette, Oblique, High Offset Caudal, #2	1



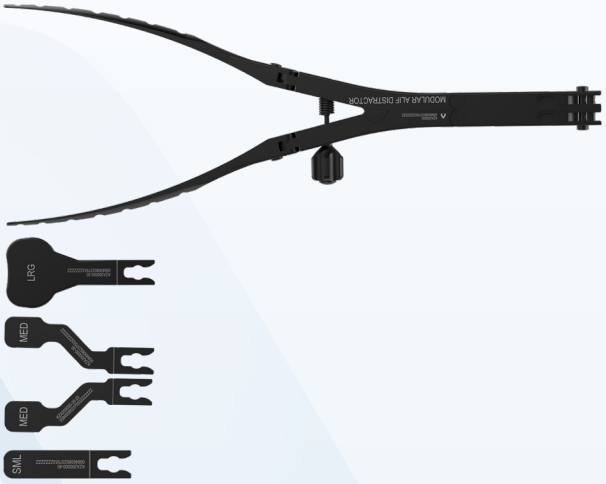
EL CAPITAN OBLIQUE ALIF ANGLED INSTRUMENTS

Part Number	Description	Qty
KZA15BF04	Uterine Curette, Oblique, High Offset Caudal, #4	1
KZA16BE02	Stirrup Curette, Oblique, High Offset Cranial, #2	1
KZA16BE04	Stirrup Curette, Oblique, High Offset Cranial, #4	1
KZA16BF02	Stirrup Curette, Oblique, High Offset Caudal, #2	1
KZA16BF04	Stirrup Curette, Oblique, High Offset Caudal, #4	1

EL CAPITAN OBLIQUE ALIF
OPTIONAL INSTRUMENTS

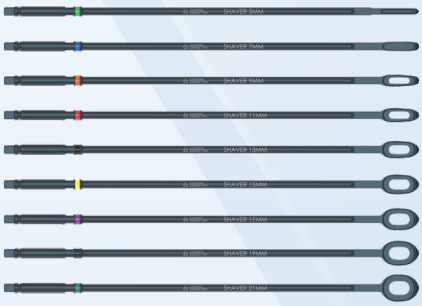
Modular ALIF Retractor (MAD-XXX)

Part Number	Description	Qty
KZA200000	MODULAR ALIF DISTRACTOR	1/OPT
KZA200000-20	MODULAR ALIF DISTRACTOR, TIPS, LARGE	2/OPT
KZA200000-30-10	MODULAR ALIF DISTRACTOR, TIPS, MEDIUM, LEFT	1/OPT
KZA200000-30-20	MODULAR ALIF DISTRACTOR, TIPS, MEDIUM, RIGHT	1/OPT
KZA200000-40	MODULAR ALIF DISTRACTOR, TIPS, SMALL	2/OPT



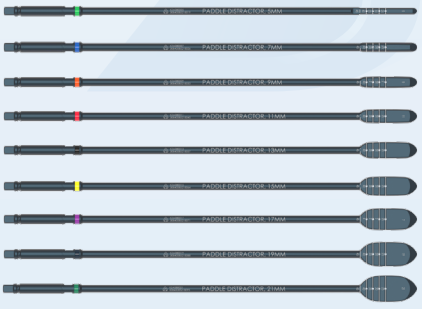
ALIF Shavers (ASHAVE-XXX)

Part Number	Description	Qty
KZA070005	ALIF Shaver, 5mm	1/OPT
KZA070007	ALIF Shaver, 7mm	1/OPT
KZA070009	ALIF Shaver, 9mm	1/OPT
KZA070011	ALIF Shaver, 11mm	1/OPT
KZA070013	ALIF Shaver, 13mm	1/OPT
KZA070015	ALIF Shaver, 15mm	1/OPT
KZA070017	ALIF Shaver, 17mm	1/OPT
KZA070019	ALIF Shaver, 19mm	1/OPT
KZA070021	ALIF Shaver, 21mm	1/OPT



ALIF Distractors (ADIST-XXX)

Part Number	Description	Qty
KZA070005	ALIF Distractor, 5mm	1/OPT
KZA070007	ALIF Distractor, 7mm	1/OPT
KZA070009	ALIF Distractor, 9mm	1/OPT
KZA070011	ALIF Distractor, 11mm	1/OPT
KZA070013	ALIF Distractor, 13mm	1/OPT
KZA070015	ALIF Distractor, 15mm	1/OPT
KZA070017	ALIF Distractor, 17mm	1/OPT
KZA070019	ALIF Distractor, 19mm	1/OPT
KZA070021	ALIF Distractor, 21mm	1/OPT



EL CAPITAN
ANTERIOR LUMBAR INTERBODY FUSION

INSTRUCTIONS FOR USE

1.0 DESCRIPTION: The EL CAPITAN ANTERIOR LUMBAR INTERBODY FUSION system are implants developed for the stabilization of the lumbar spine. The spacers are a 2-piece modular design which allows for interchangeable plate and spacer components. The plate and spacer components contain interlocking features in addition to a locking mechanism which allows for intraoperative assembly prior to implantation. The spacer components are available in a range of footprints and heights in PEEK OPTIMA LT12HA or Titanium alloy. The plates are offered in multiple fixation types and sizes to suit the individual pathology and anatomical conditions of the patient. The implants have a hollow center to allow placement of autogenous bone graft. The superior and inferior surfaces are open to promote contact of the bone graft with the vertebral end plates to allow bone growth.

2.0 MATERIALS: PEEK-OPTIMA LT120HA (PEEK-OPTIMA HA Enhanced), TI-6AL-4V ELI (ASTM F136), Tantalum (ASTM F560), Nitinol #1 (ASTM F2063).

3.0 CAUTION: Federal law (USA) restricts this device to sale and use by, or on the order of a physician. All implants are intended for single use only. The EL CAPITAN SYSTEM must not be reused under any circumstances. These instructions for use are designed to assist in use of the EL CAPITAN and are not a reference for surgical techniques.

4.0 INDICATIONS: The EL CAPITAN Anterior Lumbar Interbody System is indicated for intervertebral body fusion procedures in skeletally mature patients with degenerative disc disease (DDD) of the lumbar spine at one or two contiguous levels from L1-L2 to L5-S1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These DDD patients may also have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s). EL CAPITAN system implants are to be used with autogenous bone graft and supplemental fixation. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage. The EL CAPITAN spacer and plate assembly are an integrated interbody fusion device intended for stand-alone use when used with all titanium alloy screws.
When used with nails only the zero plate may be used and the assembly is intended for use with additional supplemental fixation that has been cleared by the FDA for use in the lumbar spine.
Hyperlordotic interbody devices (>20° lordosis) and Oblique interbody devices and EL CAPITAN X must be used with supplemental fixation (e.g. posterior fixation) that has been cleared by the FDA for use in the lumbar spine.
The EL CAPITAN X spacer may only be used with titanium alloy screws.

5.0 CONTRAINDICATIONS:

5.1 Acute or chronic infectious diseases of any etiology and localization
5.2 Signs of local inflammation
5.3 Fever or leukocytosis
5.4 Morbid obesity
5.5 Pregnancy
5.6 Metal/polymer sensitivity/allergies to the implant materials
5.7 Mental illness, alcoholism, drug abuse
5.8 Medical or surgical conditions, which would preclude the potential, benefit of spinal implant surgery
5.9 Grossly distorted anatomy due to congenital abnormalities
5.10 Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
5.11 Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery.
5.12 Any case not needing a bone graft and fusion or where fracture healing is not required
5.13 Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
5.14 Any condition that totally precludes the possibility of fusion, i.e. cancer, kidney dialysis.
5.15 Any case not described in the Indications.
5.16 Any patient unwilling to cooperate with the post-operative instructions.
5.17 Any time implant utilization would interfere with anatomical structures or expected physiological performance, or if the patient has grossly distorted anatomy caused by congenital abnormalities.
5.18 Symptomatic cardiac disease.
5.19 Systemic or terminal illness.
5.20 Prior fusion at the level to be treated.

These contraindications can be absolute or relative and must be taken into account by the physician when making surgical decisions. The list above is not exhaustive.

6.0 POSSIBLE ADVERSE EVENTS

6.1 A listing of possible adverse events includes, but is not limited to:
6.1.1 Bending or fracture of implant. Loosening of the implant.
6.1.2 Implant material sensitivity, or allergic reaction to a foreign body.
6.1.3 Infection, early or late.
6.1.4 Decrease in bone density due to stress shielding.
6.1.5 Pain, discomfort, or abnormal sensations due to the presence of the device.
6.1.6 Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Tissue damage caused by improper positioning and placement of implants or instruments.
6.1.7 Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
6.1.8 Dural tears.
6.1.9 Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
6.1.10 Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
6.1.11 Loss of bowel and/or bladder control or other types of urological system compromise.
6.1.12 Scar formation possibly causing neurological compromise around nerves and/or pain.
6.1.13 Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
6.1.14 Herniated nucleus pulposus, disc disruption, or degeneration at, above, or below the level of surgery. 14. Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
6.1.15 Graft donor site complications including pain, fracture, or wound healing problems.
6.1.16 Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
6.1.17 Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
6.1.18 Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
6.1.19 Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
6.1.20 Change in mental status.
6.1.21 Non-union (or pseudarthrosis). Delayed union. Mal-union.
6.1.22 Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function.
6.1.23 Inability to perform the activities of daily living.
6.1.24 Paralysis.
6.1.25 Death.

Note: Re-operation or revision may be necessary to correct some of these anticipated adverse events.

7.0 WARNINGS AND PRECAUTIONS: The EL CAPITAN system is intended to be used to augment the development of a spinal fusion by providing temporary stabilization while a solid fusion mass forms. This device is not intended to be the sole means of spinal support. The use of autogenous bone graft must be part of the spinal fusion procedure in which the EL CAPITAN system is utilized. Use of this product without a bone graft or in cases that develop into a non-union will not be successful. This spinal implant cannot withstand body loads without the support of bone. In this event, loosening, disassembly and/or breakage of the device will eventually occur. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are important considerations in the successful utilization of the EL CAPITAN system by the surgeon. Further, the proper selection and compliance of the patient will greatly affect the results. Patients who smoke have been shown to have an increased incidence of non-unions. These patients should be advised of this fact and warned of this consequence. Obese, malnourished, and/or alcohol and/or other drug abuse patients are also not good candidates for spine fusion. Patients with poor muscle and bone quality and/or nerve paralysis are also not good candidates for spine fusion. Patients with previous spinal surgery at the level to be treated may have different clinical outcomes compared to those without a previous surgery.
The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

CAUTION: The selection of the proper size, shape and design of the implant for each patient is crucial to the success of the procedure. The physician should always consider a variety of patient conditions including but not limited to the levels of implantation, patient weight, and patient activity level, which may have an impact on the performance of the intervertebral body fusion device.
The EL CAPITAN system has not been evaluated for safety and compatibility in the MR environment. The EL CAPITAN system has not been tested for heating, migration, or image artifact in the MR environment.
The safety of EL CAPITAN system implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

8.0 IMPLANT SELECTION: The choice of proper size, shape, and design of the implant for each patient is crucial to the success of the surgery. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely. The surgeon is responsible for this choice, which is specific to each patient. Overweight patients may be responsible for additional stresses and strains on the device, which can speed up fatigue and/or lead to deformation or failure of the implants. The surgeon must be thoroughly trained with the surgical procedure, instrumentation and implant characteristics prior to performing

surgery. The use of dissimilar materials (e.g., titanium and stainless steel) should not be used together because of the risk of galvanic corrosion. EL CAPITAN system components should not be used with components from other manufacturers.

9.0 PREOPERATIVE:

9.1 Only patients that meet the criteria described in the indications should be selected.
9.2 Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
9.3 Care should be used in the handling and storage of the implant components. The implants should not be scratched or otherwise damaged. Implants and instruments should be protected during storage especially from corrosive environments.
9.4 The type of construct to be assembled for the case should be determined prior to beginning the surgery. An adequate inventory of implant sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.
9.5 The surgeon must ensure that all necessary implants and instruments are available and on hand prior to surgery.
9.6 Since mechanical parts are involved, the surgeon should be familiar with the various components before using the equipment and should personally assemble the devices to verify that all parts and necessary instruments are present before the surgery begins. The EL CAPITAN system components are not to be combined with the components from another manufacturer
9.7 All components and instruments should be cleaned and sterilized before use. Additional sterile components should be available in case of an unexpected need.
9.8 All sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to all surgeries.
9.9 A surgical technique manual may be obtained from EL CAPITAN system from any of its representatives.

10.0 INTRAOPERATIVE

10.1 Any instruction manual should be carefully followed.
10.2 At all times, extreme caution should be used around the spinal cord and nerve roots. Damage to nerves will cause loss of neurological functions.
10.3 The implant surfaces should not be scratched or notched, since such actions may reduce the functional strength of the construct.
10.4 Autogenous bone grafts must be placed in the area to be fused and the graft should be extended from the upper to the lower vertebrae to be fused.
10.5 Bone cement should never be used with this device since this material will make removal of the components difficult or impossible and may affect the properties of the implant. The heat generated from the curing process may also cause neurological damage and bone necrosis.
10.6 Before closing the soft tissues, all of the devices should be securely seated.
10.7 Breakage, slippage, or misuse of the instruments or implant components may cause injury to the patient or the operative personnel.

11.0 POSTOPERATIVE: The physician's postoperative directions and warnings to the patient and the corresponding patient compliance are extremely important

11.1 Detailed instructions on the use and limitations of the device should be given to the patient. The risk of fatigue and/or breakage of a temporary internal fixation device during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position.
11.2 To allow the maximum chances for a successful surgical result: the patient or device should not be exposed to mechanical vibrations that may loosen the device construct. The patient should be warned of this possibility and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sport participation. The patient should be advised not to smoke or consume alcohol during the bone graft healing process.
11.3 The patient should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent physical restriction in body motion.
11.4 If a non-union develops or if the components loosen and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or non-union of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue, these stresses can cause eventual loosening or breakage of the device(s). It is important that immobilization of the spinal surgical site be maintained until firm bony union is established and confirmed by roentgenographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed.
11.5 Any decision to remove the device should take into consideration the potential risk to the patient of a second surgical procedure and the difficulty of initial implant removal.
11.6 Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the retrieved EL CAPITAN system components should ever be reused under any circumstances.

12.0 PACKAGING: Packages for each of the components should be intact upon receipt. All sets and components should be carefully checked for completeness and lack of damage prior to use. Damaged packages or products should not be used, and should be returned immediately to ASTURA MEDICAL.

13.0 CLEANING: All instruments and implants must first be cleaned before sterilization and introduction into a sterile surgical field.
Immediately after the procedure, place the instruments in a tray and cover with a towel moistened with sterile water and transport to decontamination environment. Rinse the instruments under running tap water for a minimum of 1 minute. An enzymatic cleaner bath (soak) or a solution of water and neutral pH detergent are effective in removing organic material from instruments. Use distilled water if possible. Instruments should be fully submerged for at least ten (10) minutes.
Instruments must be thoroughly cleaned. Be sure dissimilar metal instruments are separated. Confirm that all cannulated and modular instruments are fully disassembled. Ensure that all cannulas are flushed until cleaning solution runs clear and that all instruments are completely immersed. Use a small brush to remove soil from all surfaces of the instrument while fully immersed in the solution. Remove soil from hinges, jaws, tips, box locks, and ratchets. Never use steel wool, wire brushes, or highly abrasive detergents or cleaners to remove soil from instruments. Rinse instruments under running water for at least one (1) minute to remove solutions. Once instruments are cleaned and disassembled place instruments in an ultrasonic cleaner with warm enzymatic detergent for a minimum of fifteen (15) minutes. If there is any visual contamination, repeat the steps as necessary until the instruments are visually clean. Rinse instruments under running water for at least one (1) minute to remove solutions.
Instruments should never be exposed to cleaning agents containing any peroxides.
Users should periodically inspect instruments for corrosion, discoloration, etc., and properly dispose of instruments that show signs of wear and tear.
Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.
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Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

14.0 STERILIZATION: Moist heat sterilization is recommended using the Association for the Advancement of Medical Instrumentation (AAMI) guideline ST79:2006 according to the following validated cycle parameters:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Prevacuume	270°F(132°C)	4 minutes	30 minutes

Wrap tray with a towel placed between tray and FDA cleared wrap.

The Sterility Assurance Level (SAL) is 1 x 10-6, via the indicated methods. No claims of pyrogenicity are made.
Remove all packaging materials prior to sterilization. Use only sterile products in the operative field. Always immediately re-sterilize all implants and instruments used in surgery. This process must be performed before handling or returning to ASTURA MEDICAL.
This gravity displacement sterilization cycle is not considered by the Food and Drug Administration to be a standard sterilization cycle. It is the end user's responsibility to use only sterilizers and sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes that have been cleared by the Food and Drug Administration for the selected sterilization cycle specifications.
This statement is not required for the parameters listed above.
It has not been determined if reprocessing affects the chemical, phase, or structural properties of the hydroxyapatite on the EL CAPITAN Posterior Lumbar Interbody Spacer.

15.0 PRODUCT COMPLAINTS: Any Health Care Professional, who has any complaints or who has experienced any dissatisfaction relating to the product quality, durability, reliability, safety, effectiveness and/or performance, should notify ASTURA MEDICAL or its representative. Further, if any of the implanted EL CAPITAN system component(s) ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately.
If any EL CAPITAN system product ever malfunctions and may have caused or contributed to the death or serious injury of a patient, the distributor or ASTURA MEDICAL must be notified immediately by telephone, fax or in writing.
For all complaints, please include the device name, reference number, and lot number of the component(s), your name, address, and the nature of the event to help ASTURA MEDICAL understand the cause of the complaint.
If further information is needed or required, please contact using the company information listed below.

16.0 COMPANY INFORMATION

Astura Medical
4949 W Royal Ln.
Irving, TX 75063
Phone: (469) 501-5530
Email: info@asturamedical.com

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