EL CAPITAN

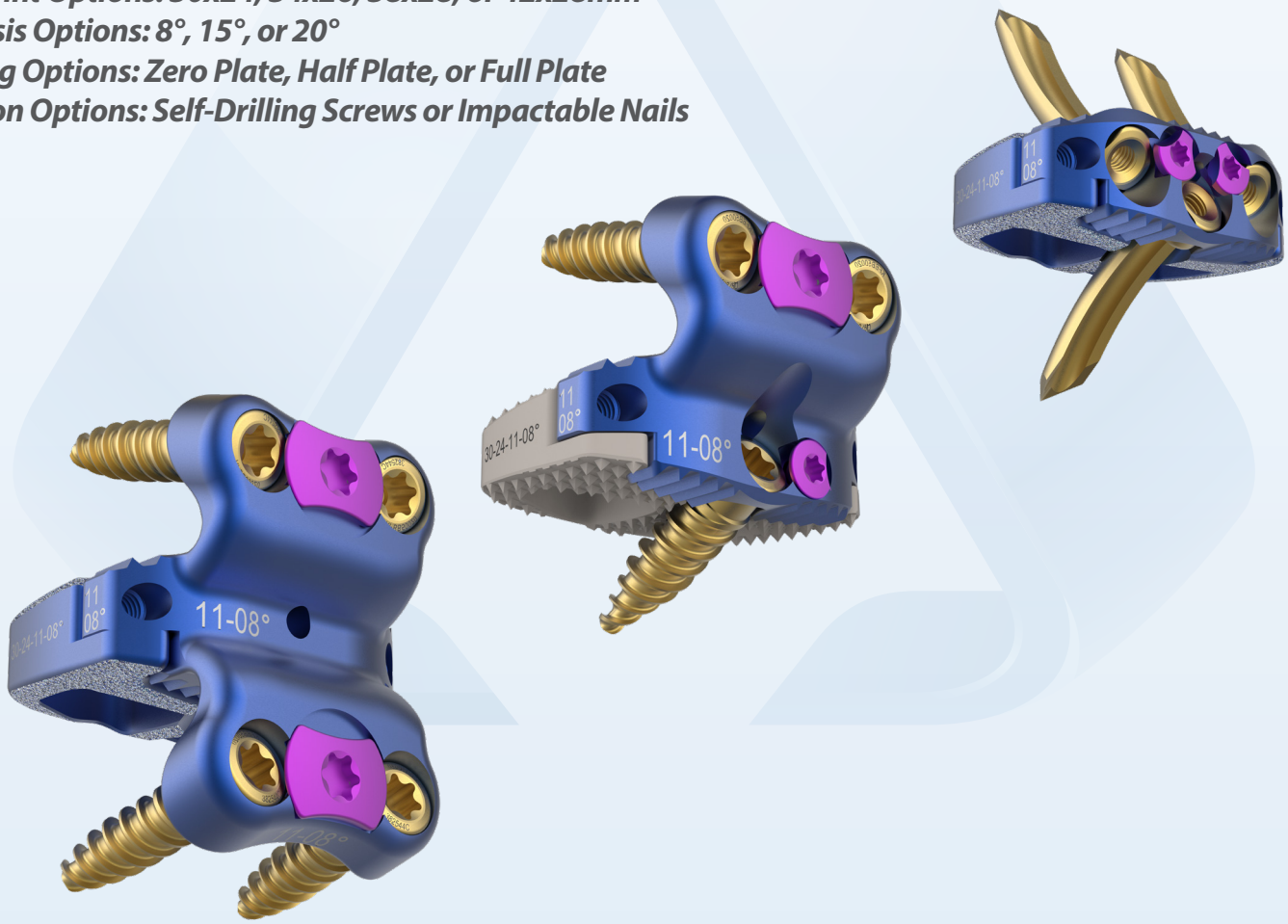
ANTERIOR LUMBAR INTERBODY FUSION

ASTURA MEDICAL

DESIGN RATIONALE

The EL CAPITAN Anterior Lumbar Interbody Fusion System by ASTURA MEDICAL is a comprehensive system that provides a complete range of anatomic spacers and fixation options for ridged anterior stabilization. The intuitive design of the system provides the versatility to accommodate a wide array of anatomical challenges to ensure an efficient, streamlined procedural sequence.

- ***EL CAPITAN Spacers are available in Acid-Etched Titanium or HA PEEK***
- ***Height Options: 11-21mm in 2mm increments***
- ***Footprint Options: 30x24, 34x26, 38x28, or 42x28mm***
- ***Lordosis Options: 8°, 15°, or 20°***
- ***Plating Options: Zero Plate, Half Plate, or Full Plate***
- ***Fixation Options: Self-Drilling Screws or Impactable Nails***



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°

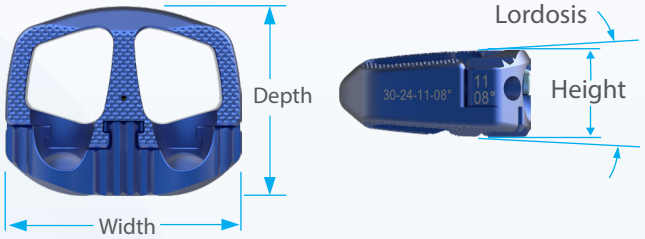
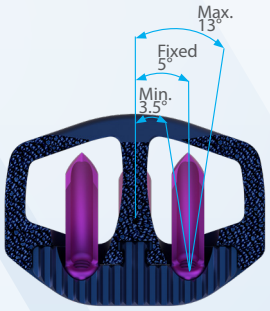
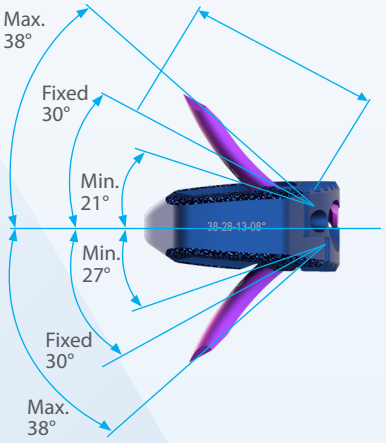
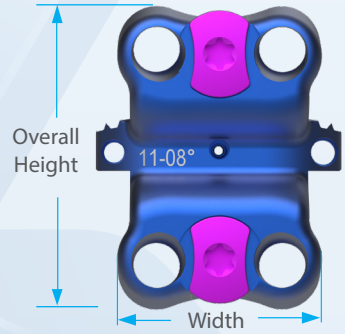
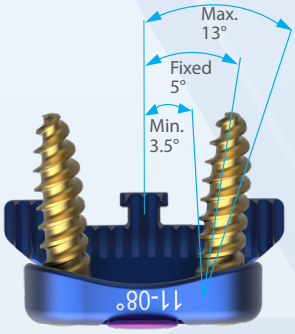


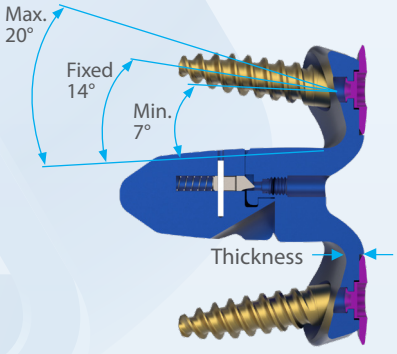
PLATE TYPES AND SIZING				
Type	Spacer Height (mm)	Overall Height (mm)	Width (mm)	Thickness (mm)
Zero	11,13,15,17,19, 21	Spacer Height	24.5	N/A
Half	11,13,15,17,19, 21	21, 23, 25, 27, 29, 31	24.5	3
Full	11,13,15,17,19, 21	32, 34, 36, 38, 40, 42	24.5	3



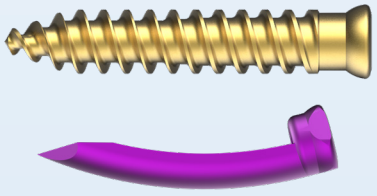








FIXATION TYPES AND SIZING			
Type	Constraint	Diameters (mm)	Lengths (mm)
Self-Drilling Screws	Variable	5.0 or 5.5	20, 25, 30
Nails	Variable	5.5	20, 25, 30



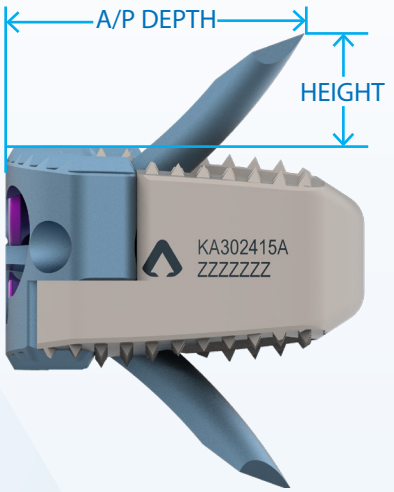
NAIL AND SCREW SIZING

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

ZERO PROFILE PLATE WITH NAILS

NAIL LENGTH	A/P DEPTH	HEIGHT
20MM	20.26	8.32
25MM	22.75	13.25
30MM	24.52	18.65

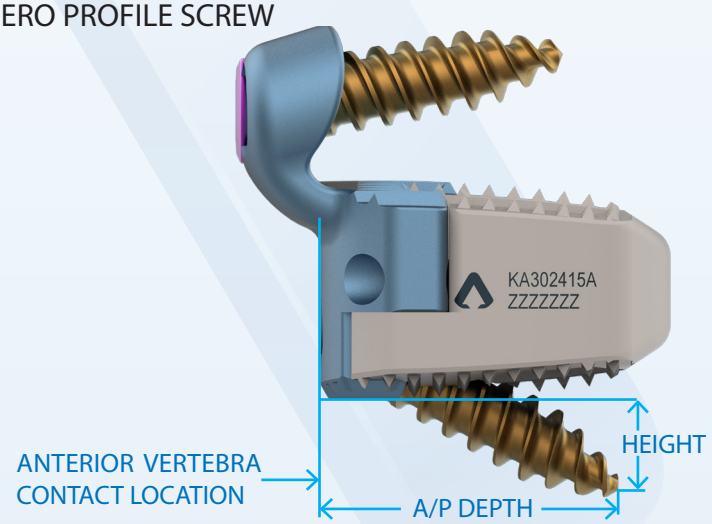
SPACER SIZE	MAX NAIL LENGTH
30X24	25MM
34X26	30MM
38X28	30MM
42X28	30MM



HALF PLATE WITH ZERO PROFILE SCREW

SCREW LENGTH	A/P DEPTH	HEIGHT
20MM	21.81	9.93
25MM	26.45	11.78
30MM	31.10	13.64

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



1.0 APPROACH

1.1 Access the disc using the preferred anterior approach using a standard anterior retraction system.

2.0 ACCESS

2.1 Use a Midline Marking Pin (KZA010000) in combination with fluoroscopy to verify the operative level and midline of the disc. If desired, the Modular Rotating Distractor Handle (KZA170000) can be used to insert or remove the Midline Marking Pin.

2.2 Use the Annulotomy Guides (KZA0200XX) to ensure adequate retraction and to identify the borders of the annulotomy.

3.0 DISC PREPARATION

3.1 Incise the disc using the Annulotomy Knife (KZA030000) to create a rectangular channel matching the chosen Annulotomy Guide (KZA0200XX).

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

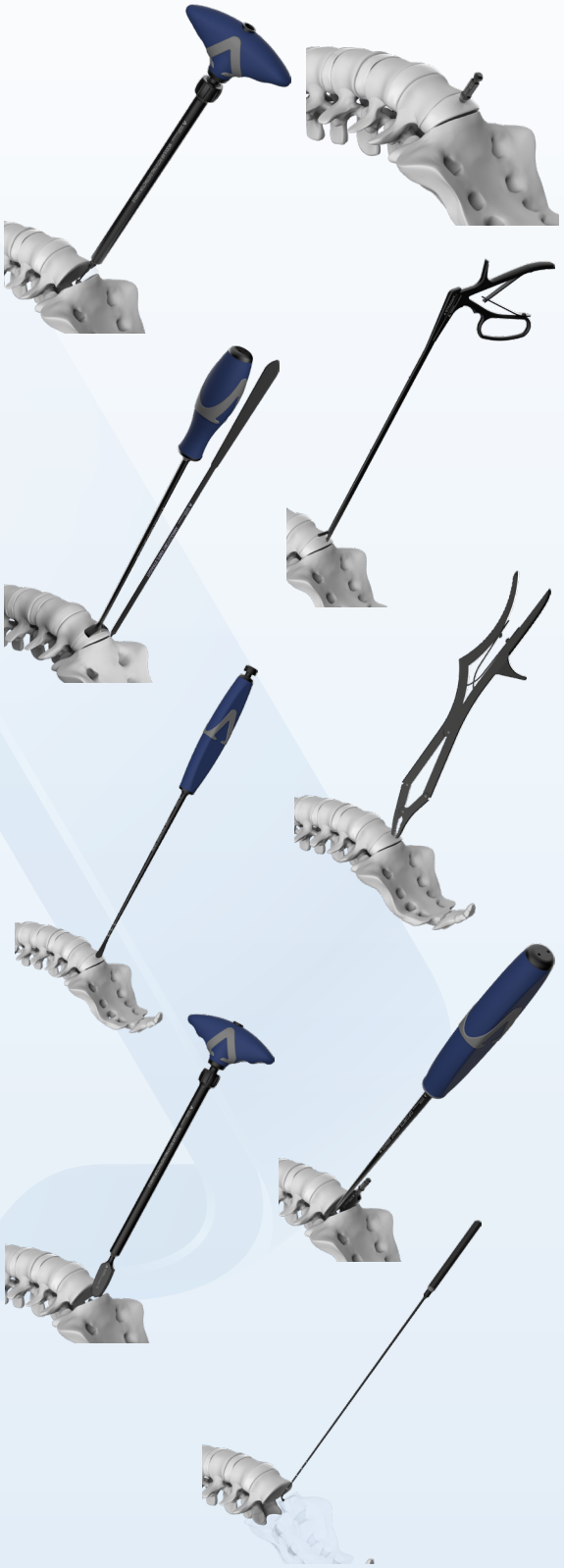
3.3 Utilize the Osteotome (KZA11SZXX) or Cobb (KZA12SZXX) to assist in removing intervertebral disc material.

3.4 Utilize the Kerrisons (KZA10SZXX) and Lexcel (KZA060000) 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 space, then rotating 90 degrees to distract the endplates. 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.



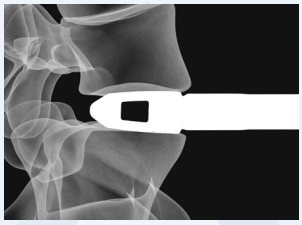
4.0 IMPLANT TRIALING ASSEMBLY AND INSERTION

4.1 Implant Trialing

4.1.1 Choose the appropriate footprint Trial (KZB03XXXX) based on the previously used Annulotomy Guide (KZA0200XX). Attach the Trial (KZB03XXXX) to the Trial Inserter (KZB020000) by aligning the pin in the distal end of the Trial Inserter with the hole 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. Flouroscopy can be used to confirm the desired anatomic alignment.

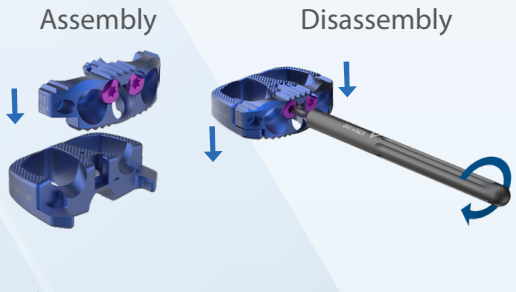
4.1.3 Attach the Slaphammer (KZB120000) to the proximal portion of the inserter to facilitate removal of the Trials from the disc space.



4.2 Implant Assembly

4.2.1 Select the Spacer (KAXXXXXXX, KBXXXXXXX) component that matches the chosen Trial. Select the desired Plate component which matches the height and lordosis of the chosen Spacer. Attach the Plate (KDAXXXXXX, KDBXXXXXX, KDCXXXXXX) 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 components can be removed by threading the Implant Disassembly Tool (KZB010000) into the center threaded hole within the plate, then sliding the two components away from one another.



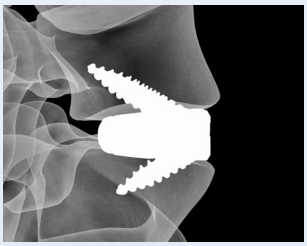
4.3 Implant Insertion and Screw Fixation

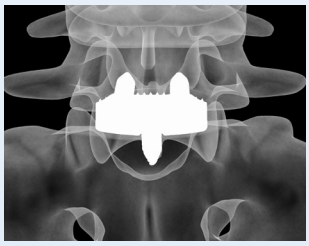
4.3.1 Spacer Insertion

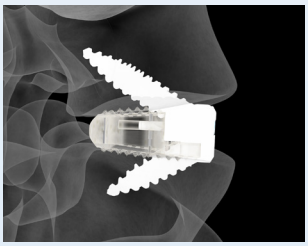
4.3.1.1 Obtain the Implant Inserter (KZB070000), then identify the corresponding Screw Guide (KZB0500XX) that matches the chosen implant height. Attach the Screw Guide to the Implant Inserter (KZB070000) by aligning the arrows, then sliding the two components together.

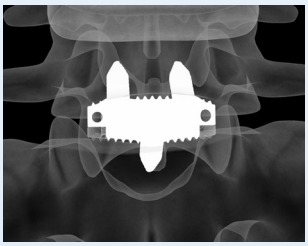
4.3.1.2 Once the Screw Guide is assembled to the Spacer Inserter, align the implant to the inserter, then thread the proximal knob until the Implant is secure.

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 fluoroscopy.









4.3.1.4 Screw Preparation

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

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

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

4.3.1.4.1.3 Place the distal end of the Drill into the Screw Guide (KZB0500XX) then advance the Drill until bottomed out.

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

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

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

4.3.1.4.2.1 Attach the Variable Angle Drill, Short (KZC110010) to the Modular Egg Handle or Power Driver.

4.3.1.4.2.2 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.

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

4.3.1.4.2.4 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.

4.3.1.4.3 Variable Angle Self-Centering **(with Inserter attached)**

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

4.3.2.4.3.2 Place the Variable Angle Drill Guide Tip into the Screw Guide, then advance the Variable Angle Drill until bottomed out.

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

4.3.2.4.3.4 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 prepared hole.

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

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

4.3.1.4.4.2 Place the Drill Bit into the Screw Guide, then advance the Fixed Angle Driver until the Drill Bit is bottomed out.

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

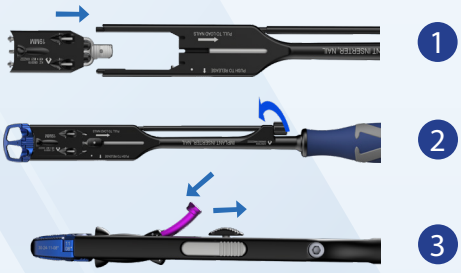
4.3.1.4.4.4 Attach the Screwdriver Bit to the distal end of the Fixed Angle Driver, then connect the the Modular Egg Handle to the proximal end. Attach the Screw by pressing the tip of the Screwdriver Bit (KZC140010) into the Screw creating a "Stick Fit", then insert the Screw into the prepared hole.

4.3.1.5 Fixed Angle (Awl) (KZC200000)

4.3.1.5.1 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.

4.3.1.6 Detaching Spacer

4.3.1.6.1 Unthread the proximal knob of the Implant 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.



4.4 Implant Insertion or Nail Fixation

4.4.1 Obtain the Implant Inserter, then identify the corresponding Nail Guide (KZB0800XX) that matches the chosen Spacer height. Attach the Nail Guide to the Spacer Inserter by aligning the arrows, then sliding the two components together.

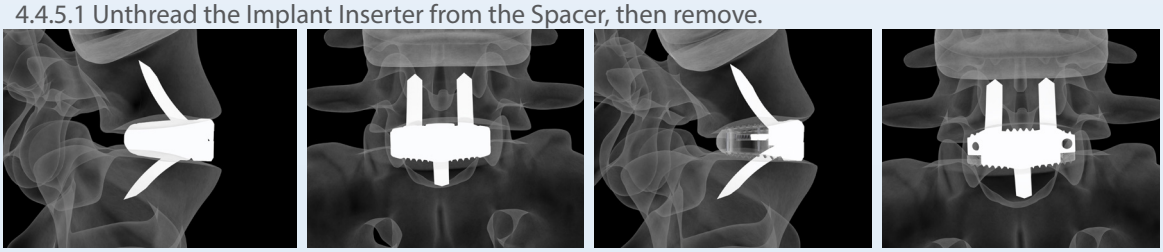
4.4.2 Once the Nail Guide is assembled to the Implant Inserter, align the Implant (KDAXX000X) to the inserter, then thread the lateral knob until the Implant is secure.

4.4.3 Once the Spacer is attached, pull the slide button back until the button locks into the proximal position. Pull the button back, then insert the Nail (KF00000XX) until the Nail seats flush in each one of the 3 channels. Release the slide button to capture the nails.

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.

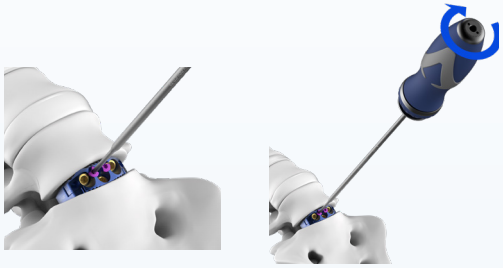
4.4.5.1 Unthread the Implant Inserter from the Spacer, then remove.



4.5 Implant 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:

* (Zero Plate and Half Plate Lower Cam (T10) - 180°
Half Plate Upper Cam and Full Plate (T20) - 90°)

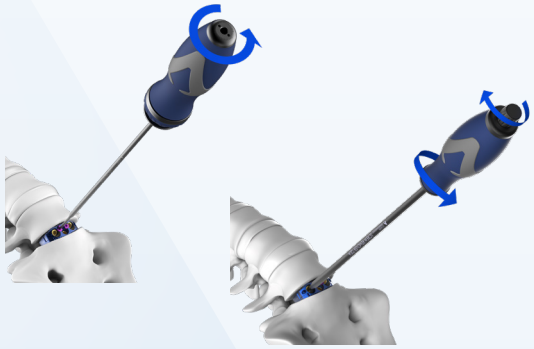


4.6 Implant Removal

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 **(*)** 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.



4.6.2 Nail Removal

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

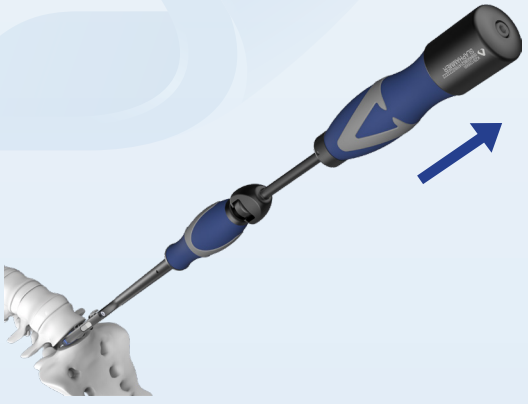
4.6.2.2 Attach the Nail Remover (KZC070000) to the nail by threading the proximal knob clockwise until resistance is felt. Once securely attached, connect the slaphammer (KZB120000) to the Nail Remover and reverse impact in an arched motion until the nail is removed.

4.6.3 Spacer Removal

4.6.3.1 Obtain the Spacer Inserter (KZB070000) then identify the corresponding Screw Guide (KZB0500XX) that matches the chosen Implant height. Attach the Screw Guide to the Spacer Inserter, then slide the two components together.

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

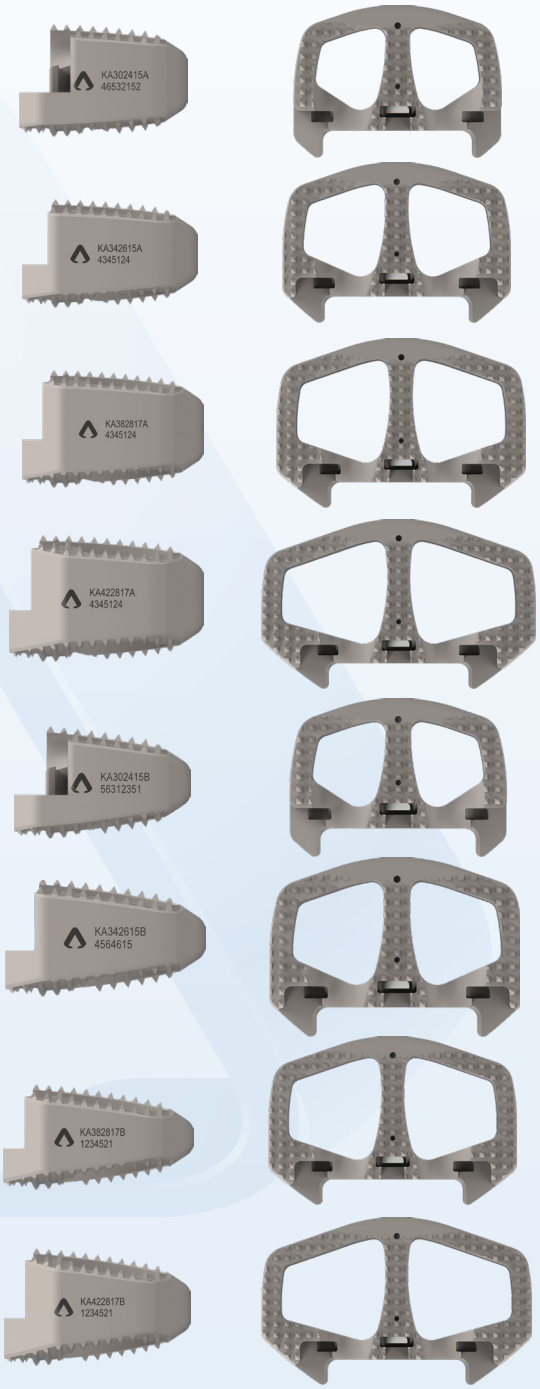
4.6.3.2 Assemble the Slap Hammer to the Spacer Inserter, then reverse impact until the Spacer is removed.



EL CAPITAN ANTERIOR LUMBAR INTERBODY FUSION HA PEEK OFFERING

ALIF SPACER, HA PEEK

Part Number	Description	Qty
KA302411A	ALIF Spacer, HA PEEK, 30mm x 24mm x 11mm, 8°, Non-Sterile	2
KA302413A	ALIF Spacer, HA PEEK, 30mm x 24mm x 13mm, 8°, Non-Sterile	2
KA302415A	ALIF Spacer, HA PEEK, 30mm x 24mm x 15mm, 8°, Non-Sterile	2
KA302417A	ALIF Spacer, HA PEEK, 30mm x 24mm x 17mm, 8°, Non-Sterile	2
KA302419A	ALIF Spacer, HA PEEK, 30mm x 24mm x 19mm, 8°, Non-Sterile	2
KA342611A	ALIF Spacer, HA PEEK, 34mm x 26mm x 11mm, 8°, Non-Sterile	2
KA342613A	ALIF Spacer, HA PEEK, 34mm x 26mm x 13mm, 8°, Non-Sterile	2
KA342615A	ALIF Spacer, HA PEEK, 34mm x 26mm x 15mm, 8°, Non-Sterile	2
KA342617A	ALIF Spacer, HA PEEK, 34mm x 26mm x 17mm, 8°, Non-Sterile	2
KA342619A	ALIF Spacer, HA PEEK, 34mm x 26mm x 19mm, 8°, Non-Sterile	2
KA382811A	ALIF Spacer, HA PEEK, 38mm x 28mm x 11mm, 8°, Non-Sterile	2
KA382813A	ALIF Spacer, HA PEEK, 38mm x 28mm x 13mm, 8°, Non-Sterile	2
KA382815A	ALIF Spacer, HA PEEK, 38mm x 28mm x 15mm, 8°, Non-Sterile	2
KA382817A	ALIF Spacer, HA PEEK, 38mm x 28mm x 17mm, 8°, Non-Sterile	2
KA382819A	ALIF Spacer, HA PEEK, 38mm x 28mm x 19mm, 8°, Non-Sterile	2
KA382821A	ALIF Spacer, HA PEEK, 38mm x 28mm x 21mm, 8°, Non-Sterile	2
KA422811A	ALIF Spacer, HA PEEK, 42mm x 28mm x 11mm, 8°, Non-Sterile	2
KA422813A	ALIF Spacer, HA PEEK, 42mm x 28mm x 13mm, 8°, Non-Sterile	2
KA422815A	ALIF Spacer, HA PEEK, 42mm x 28mm x 15mm, 8°, Non-Sterile	2
KA422817A	ALIF Spacer, HA PEEK, 42mm x 28mm x 17mm, 8°, Non-Sterile	2
KA422819A	ALIF Spacer, HA PEEK, 42mm x 28mm x 19mm, 8°, Non-Sterile	2
KA422821A	ALIF Spacer, HA PEEK, 42mm x 28mm x 21mm, 8°, Non-Sterile	2
KA302411B	ALIF Spacer, HA PEEK, 30mm x 24mm x 11mm, 15°, Non-Sterile	2
KA302413B	ALIF Spacer, HA PEEK, 30mm x 24mm x 13mm, 15°, Non-Sterile	2
KA302415B	ALIF Spacer, HA PEEK, 30mm x 24mm x 15mm, 15°, Non-Sterile	2
KA302417B	ALIF Spacer, HA PEEK, 30mm x 24mm x 17mm, 15°, Non-Sterile	2
KA302419B	ALIF Spacer, HA PEEK, 30mm x 24mm x 19mm, 15°, Non-Sterile	2
KA342611B	ALIF Spacer, HA PEEK, 34mm x 26mm x 11mm, 15°, Non-Sterile	2
KA342613B	ALIF Spacer, HA PEEK, 34mm x 26mm x 13mm, 15°, Non-Sterile	2
KA342615B	ALIF Spacer, HA PEEK, 34mm x 26mm x 15mm, 15°, Non-Sterile	2
KA342617B	ALIF Spacer, HA PEEK, 34mm x 26mm x 17mm, 15°, Non-Sterile	2
KA342619B	ALIF Spacer, HA PEEK, 34mm x 26mm x 19mm, 15°, Non-Sterile	2
KA382811B	ALIF Spacer, HA PEEK, 38mm x 28mm x 11mm, 15°, Non-Sterile	2
KA382813B	ALIF Spacer, HA PEEK, 38mm x 28mm x 13mm, 15°, Non-Sterile	2
KA382815B	ALIF Spacer, HA PEEK, 38mm x 28mm x 15mm, 15°, Non-Sterile	2
KA382817B	ALIF Spacer, HA PEEK, 38mm x 28mm x 17mm, 15°, Non-Sterile	2
KA382819B	ALIF Spacer, HA PEEK, 38mm x 28mm x 19mm, 15°, Non-Sterile	2
KA382821B	ALIF Spacer, HA PEEK, 38mm x 28mm x 21mm, 15°, Non-Sterile	2
KA422811B	ALIF Spacre, HA PEEK, 42mm x 28mm x 11mm, 15°, Non-Sterile	2
KA422813B	ALIF Spacer, HA PEEK, 42mm x 28mm x 13mm, 15°, Non-Sterile	2
KA422815B	ALIF Spacer, HA PEEK, 42mm x 28mm x 15mm, 15°, Non-Sterile	2
KA422817B	ALIF Spacer, HA PEEK, 42mm x 28mm x 17mm, 15°, Non-Sterile	2
KA422819B	ALIF Spacer, HA PEEK, 42mm x 28mm x 19mm, 15°, Non-Sterile	2
KA422821B	ALIF Spacer, HA PEEK, 42mm x 28mm x 21mm, 15°, Non-Sterile	2



EL CAPITAN ANTERIOR LUMBAR INTERBODY FUSION HA PEEK OFFERING

ALIF SPACER, HA PEEK

Part Number	Descript	Qty
KA342615C	ALIF Spacer, HA PEEK, 34mm x 26mm x 15mm, 20°, Non-Sterile	2
KA342617C	ALIF Spacer, HA PEEK, 34mm x 26mm x 17mm, 20°, Non-Sterile	2
KA342619C	ALIF Spacer, HA PEEK, 34mm x 26mm x 19mm, 20°, Non-Sterile	2
KA342621C	ALIF Spacer, HA PEEK, 34mm x 26mm x 21mm, 20°, Non-Sterile	2
KA382815C	ALIF Spacer, HA PEEK, 38mm x 28mm x 15mm, 20°, Non-Sterile	2
KA382817C	ALIF Spacer, HA PEEK, 38mm x 28mm x 17mm, 20°, Non-Sterile	2
KA382819C	ALIF Spacer, HA PEEK, 38mm x 28mm x 19mm, 20°, Non-Sterile	2
KA382821C	ALIF Spacer, HA PEEK, 38mm x 28mm x 21mm, 20°, Non-Sterile	2
KA422815C	ALIF Spacer, HA PEEK, 42mm x 28mm x 15mm, 20°, Non-Sterile	2
KA422817C	ALIF Spacer, HA PEEK, 42mm x 28mm x 17mm, 20°, Non-Sterile	2
KA422819C	ALIF Spacer, HA PEEK, 42mm x 28mm x 19mm, 20°, Non-Sterile	2
KA422821C	ALIF Spacer, HA PEEK, 42mm x 28mm x 21mm, 20°, Non-Sterile	2

EL CAPITAN ANTERIOR LUMBAR INTERBODY FUSION ACID-ETCHED TITANIUM OFFERING

ALIF SPACER, ACID-ETCHED TITANIUM

Part Number	Description	Qty
KB302411A	ALIF Spacer, Acid-etched Titanium, 30mm x 24mm x 11mm, 8°, Non-Sterile	2
KB302413A	ALIF Spacer, Acid-etched Titanium, 30mm x 24mm x 13mm, 8°, Non-Sterile	2
KB302415A	ALIF Spacer, Acid-etched Titanium, 30mm x 24mm x 15mm, 8°, Non-Sterile	2
KB302417A	ALIF Spacer, Acid-etched Titanium, 30mm x 24mm x 17mm, 8°, Non-Sterile	2
KB302419A	ALIF Spacer, Acid-etched Titanium, 30mm x 24mm x 19mm, 8°, Non-Sterile	2
KB342611A	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 11mm, 8°, Non-Sterile	2
KB342613A	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 13mm, 8°, Non-Sterile	2
KB342615A	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 15mm, 8°, Non-Sterile	2
KB342617A	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 17mm, 8°, Non-Sterile	2
KB342619A	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 19mm, 8°, Non-Sterile	2
KB382811A	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 11mm, 8°, Non-Sterile	2
KB382813A	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 13mm, 8°, Non-Sterile	2
KB382815A	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 15mm, 8°, Non-Sterile	2
KB382817A	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 17mm, 8°, Non-Sterile	2
KB382819A	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 19mm, 8°, Non-Sterile	2
KB382821A	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 21mm, 8°, Non-Sterile	2
KB422811A	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 11mm, 8°, Non-Sterile	2
KB422813A	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 13mm, 8°, Non-Sterile	2
KB422815A	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 15mm, 8°, Non-Sterile	2
KB422817A	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 17mm, 8°, Non-Sterile	2
KB422819A	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 19mm, 8°, Non-Sterile	2
KB422821A	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 21mm, 8°, Non-Sterile	2
KB302411B	ALIF Spacer, Acid-etched Titanium, 30mm x 24mm x 11mm, 15°, Non-Sterile	2
KB302413B	ALIF Spacer, Acid-etched Titanium, 30mm x 24mm x 13mm, 15°, Non-Sterile	2
KB302415B	ALIF Spacer, Acid-etched Titanium, 30mm x 24mm x 15mm, 15°, Non-Sterile	2
KB302417B	ALIF Spacer, Acid-etched Titanium, 30mm x 24mm x 17mm, 15°, Non-Sterile	2
KB302419B	ALIF Spacer, Acid-etched Titanium, 30mm x 24mm x 19mm, 15°, Non-Sterile	2
KB342611B	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 11mm, 15°, Non-Sterile	2
KB342613B	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 13mm, 15°, Non-Sterile	2
KB342615B	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 15mm, 15°, Non-Sterile	2
KB342617B	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 17mm, 15°, Non-Sterile	2
KB342619B	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 19mm, 15°, Non-Sterile	2
KB382811B	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 11mm, 15°, Non-Sterile	2
KB382813B	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 13mm, 15°, Non-Sterile	2
KB382815B	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 15mm, 15°, Non-Sterile	2
KB382817B	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 17mm, 15°, Non-Sterile	2
KB382819B	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 19mm, 15°, Non-Sterile	2
KB382821B	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 21mm, 15°, Non-Sterile	2
KB422811B	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 11mm, 15°, Non-Sterile	2
KB422813B	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 13mm, 15°, Non-Sterile	2
KB422815B	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 15mm, 15°, Non-Sterile	2
KB422817B	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 17mm, 15°, Non-Sterile	2
KB422819B	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 19mm, 15°, Non-Sterile	2
KB422821B	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 21mm, 15°, Non-Sterile	2

EL CAPITAN ANTERIOR LUMBAR INTERBODY FUSION
ACID-ETCHED TITANIUM OFFERING

ALIF SPACER, ACID-ETCHED TITANIUM

Part Number	Description	Qty
KB342615C	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 15mm, 20°, Non-Sterile	2
KB342617C	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 17mm, 20°, Non-Sterile	2
KB342619C	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 19mm, 20°, Non-Sterile	2
KB342621C	ALIF Spacer, Acid-etched Titanium, 34mm x 26mm x 21mm, 20°, Non-Sterile	2
KB382815C	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 15mm, 20°, Non-Sterile	2
KB382817C	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 17mm, 20°, Non-Sterile	2
KB382819C	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 19mm, 20°, Non-Sterile	2
KB382821C	ALIF Spacer, Acid-etched Titanium, 38mm x 28mm x 21mm, 20°, Non-Sterile	2
KB422815C	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 15mm, 20°, Non-Sterile	2
KB422817C	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 17mm, 20°, Non-Sterile	2
KB422819C	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 19mm, 20°, Non-Sterile	2
KB422821C	ALIF Spacer, Acid-etched Titanium, 42mm x 28mm x 21mm, 20°, Non-Sterile	2

EL CAPITAN ANTERIOR LUMBAR INTERBODY FUSION PLATE OFFERING

ALIF PLATE, ZERO-PROFILE, 8°

Part Number	Description	Qty
KDA11000A	ALIF Zero-Profile, 11mm, 8°	2
KDA13000A	ALIF Zero-Profile, 13mm, 8°	2
KDA15000A	ALIF Zero-Profile, 15mm, 8°	2
KDA17000A	ALIF Zero-Profile, 17mm, 8°	2
KDA19000A	ALIF Zero-Profile, 19mm, 8°	2
KDA21000A	ALIF Zero-Profile, 21mm, 8°	2

ALIF PLATE, ZERO-PROFILE, 15°

Part Number	Description	Qty
KDA11000B	ALIF Zero-Profile, 11mm, 15°	2
KDA13000B	ALIF Zero-Profile, 13mm, 15°	2
KDA15000B	ALIF Zero-Profile, 15mm, 15°	2
KDA17000B	ALIF Zero-Profile, 17mm, 15°	2
KDA19000B	ALIF Zero-Profile, 19mm, 15°	2
KDA21000B	ALIF Zero-Profile, 21mm, 15°	2

ALIF PLATE, ZERO-PROFILE, 20°

Part Number	Description	Qty
KDA15000C	ALIF Zero-Profile, 15mm, 20°	2
KDA17000C	ALIF Zero-Profile, 17mm, 20°	2
KDA19000C	ALIF Zero-Profile, 19mm, 20°	2
KDA21000C	ALIF Zero-Profile, 21mm, 20°	2

ALIF PLATE, HALF-PROFILE, 8°

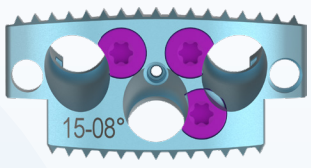
Part Number	Description	Qty
KDB11000A	ALIF Half-Profile, 11mm, 8°	1
KDB13000A	ALIF Half-Profile, 13mm, 8°	1
KDB15000A	ALIF Half-Profile, 15mm, 8°	1
KDB17000A	ALIF Half-Profile, 17mm, 8°	1
KDB19000A	ALIF Half-Profile, 19mm, 8°	1
KDB21000A	ALIF Half-Profile, 21mm, 8°	1

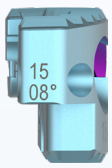
ALIF PLATE, HALF-PROFILE, 15°

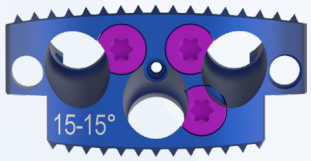
Part Number	Description	Qty
KDB11000B	ALIF Half-Profile, 11mm, 15°	1
KDB13000B	ALIF Half-Profile, 13mm, 15°	1
KDB15000B	ALIF Half-Profile, 15mm, 15°	1
KDB17000B	ALIF Half-Profile, 17mm, 15°	1
KDB19000B	ALIF Half-Profile, 19mm, 15°	1
KDB21000B	ALIF Half-Profile, 21mm, 15°	1

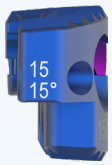
ALIF PLATE, HALF-PROFILE, 20°

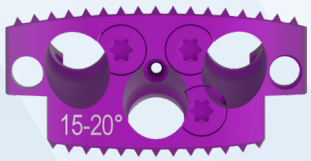
Part Number	Description	Qty
KDB15000C	ALIF Half-Profile, 15mm, 20°	1
KDB17000C	ALIF Half-Profile, 17mm, 20°	1
KDB19000C	ALIF Half-Profile, 19mm, 20°	1
KDB21000C	ALIF Half-Profile, 21mm, 20°	1

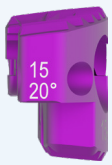


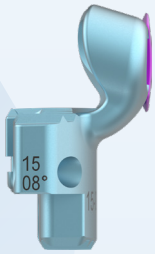












EL CAPITAN ANTERIOR LUMBAR INTERBODY FUSION PLATE OFFERING

ALIF PLATE, FULL, 8°

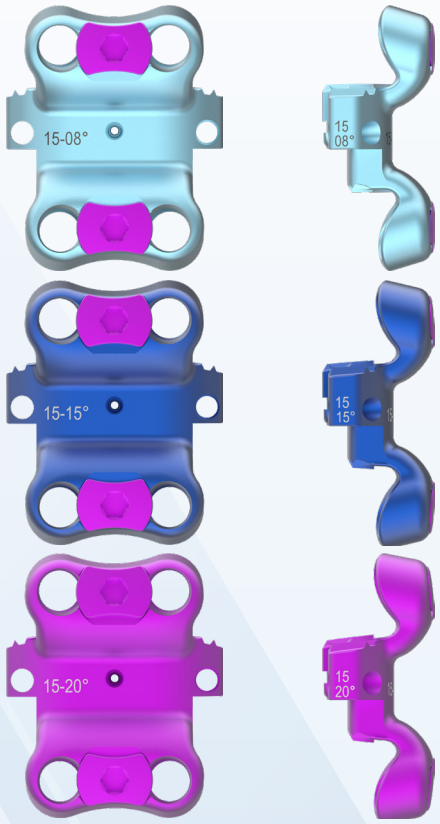
Part Number	Description	Qty
KDC11000A	ALIF Plate, Full, 11mm, 8°	1
KDC13000A	ALIF Plate, Full, 13mm, 8°	1
KDC15000A	ALIF Plate, Full, 15mm, 8°	1
KDC17000A	ALIF Plate, Full, 17mm, 8°	1
KDC19000A	ALIF Plate, Full, 19mm, 8°	1
KDC21000A	ALIF Plate, Full, 21mm, 8°	1

ALIF PLATE, FULL, 15°

Part Number	Description	Qty
KDC11000B	ALIF Plate, Full, 11mm, 15°	1
KDC13000B	ALIF Plate, Full, 13mm, 15°	1
KDC15000B	ALIF Plate, Full, 15mm, 15°	1
KDC17000B	ALIF Plate, Full, 17mm, 15°	1
KDC19000B	ALIF Plate, Full, 19mm, 15°	1
KDC21000B	ALIF Plate, Full, 21mm, 15°	1

ALIF PLATE, FULL, 20°

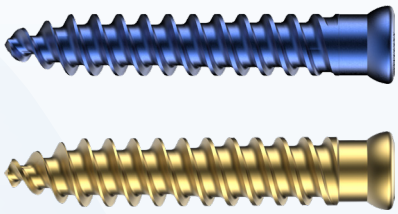
Part Number	Description	Qty
KDC15000C	ALIF Plate, Full, 15mm, 20°	1
KDC17000C	ALIF Plate, Full, 17mm, 20°	1
KDC19000C	ALIF Plate, Full, 19mm, 20°	1
KDC21000C	ALIF Plate, Full, 21mm, 20°	1



EL CAPITAN ANTERIOR LUMBAR INTERBODY FUSION PLATE SCREWS AND NAILS OFFERING

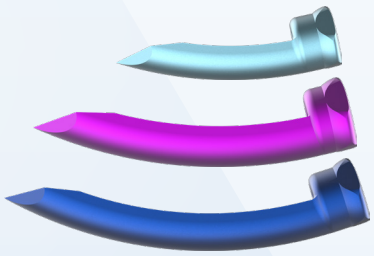
ALIF SCREWS, SELF-DRILLING, VARIABLE

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



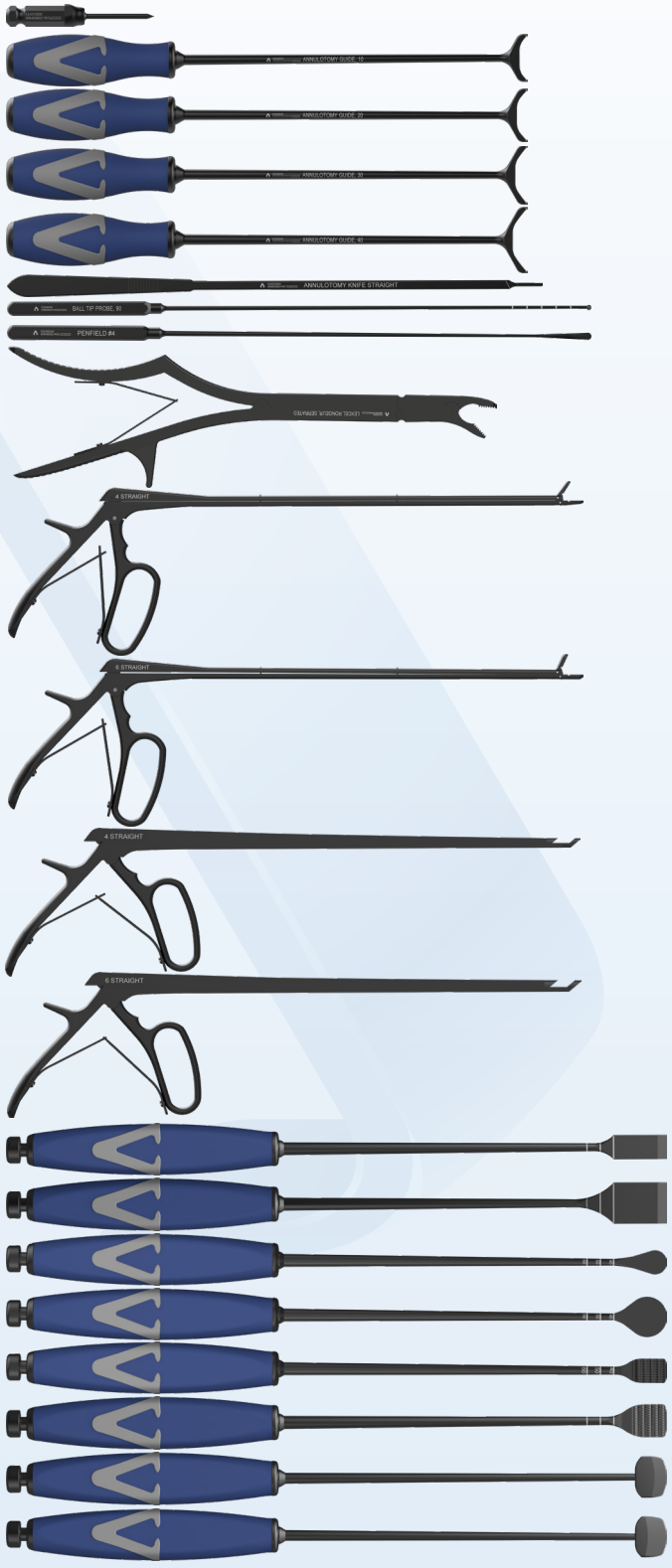
ALIF NAILS

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 ANTERIOR LUMBAR INTERBODY FUSION 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 ANTERIOR LUMBAR INTERBODY FUSION INSTRUMENT OFFERING

Part Number	Description	Qty
KZA14SQ04	Cup Curette, Straight, #4 With Teeth	1
KZA14SQ06	Cup Curette, Straight #6 With Teeth	1
KZA14SP04	Cup Curette, Up, 30^0 #4 With Teeth	1
KZA14SP06	Cup Curette, Up, 30^0 #6 With Teeth	1
KZA14SY04	Cup Curette, Up, 90^0 #4 With Teeth	1
KZA14SY06	Cup Curette, Up, 90^0 #6 With Teeth	1
KZA14ST04	Cup Curette, Down, 30^0 #4 With Teeth	1
KZA14ST06	Cup Curette, Down, 30^0 #6 With Teeth	1
KZA14SV04	Cup Curette, Down 90^0, #4 With Teeth	1
KZA14SV06	Cup Curette, Down 90^0, #6, With Teeth	1
KZA15SZ04	Uterine Curette, Straight, #4	OPT
KZA15SZ06	Uterine Curette, Straight, #6	OPT
KZA16SZ06	Stirrup Curette, Straight, #6	1
KZA16SZ08	Stirrup Curette, Straight, #8	1
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

ALIF SPACER INSTRUMENTS

Part Number	Description	Qty
KZB010000	Implant Disassembly Driver	1
KZB020000	Trial Inserter	2
KZB050000	Screw Guide, Zero-Profile, Blank	1
KZB050011	Screw Guide, Zero-Profile, 11-13mm	1
KZB050015	Screw Guide, Zero-Profile, 15mm	1
KZB050017	Screw Guide, Zero-Profile, 17mm	1
KZB050019	Screw Guide, Zero-Profile, 19mm	1
KZB050021	Screw Guide, Zero-Profile, 21mm	1
KZB060011	Screw Guide, Half-Profile and Full Plate, 11mm	1
KZB060013	Screw Guide, Half-Profile and Full Plate, 13mm	1
KZB060015	Screw Guide, Half-Profile and Full Plate, 15mm	1
KZB060017	Screw Guide, Half-Profile and Full Plate, 17mm	1
KZB060019	Screw Guide, Half-Profile and Full Plate, 19mm	1
KZB060021	Screw Guide, Half-Profile and Full Plate, 21mm	1
KZB070000	Implant Inserter	1

ALIF SPACER INSTRUMENTS

Part Number	Description	Qty	
KZB080011	Nail Guide, 11-13mm	1	
KZB080015	Nail Guide, 15mm	1	
KZB080017	Nail Guide, 17mm	1	
KZB080019	Nail Guide, 19mm	1	
KZB080021	Nail Guide, 21mm	1	
KZB090000	Inserter Knob Driver	1	
KZB100000	Nail Impactor	1	
KZB110000	Mallet	1	
KZB120000	Slaphammer	1	
KZB130000	Straight Tamp	1	

ALIF TRIALS

ALIF TRIAL, SMALL, 8°

Part Number	Description	Qty
KZB03A11A	ALIF Trial, Small, 11mm, 8°	1
KZB03A13A	ALIF Trial, Small, 13mm, 8°	1
KZB03A15A	ALIF Trial, Small, 15mm, 8°	1
KZB03A17A	ALIF Trial, Small, 17mm, 8°	1
KZB03A19A	ALIF Trial, Small, 19mm, 8°	1
KZB03A21A	ALIF Trial, Small, 21mm, 8°	1

ALIF TRIAL, MEDIUM, 8°

Part Number	Description	Qty
KZB03B11A	ALIF Trial, Medium, 11mm, 8°	1
KZB03B13A	ALIF Trial, Medium, 13mm, 8°	1
KZB03B15A	ALIF Trial, Medium, 15mm, 8°	1
KZB03B17A	ALIF Trial, Medium, 17mm, 8°	1
KZB03B19A	ALIF Trial, Medium, 19mm, 8°	1
KZB03B21A	ALIF Trial, Medium, 21mm, 8°	1

ALIF TRIAL, LARGE, 8°

Part Number	Description	Qty
KZB03C11A	ALIF Trial, Large, 11mm, 8°	1
KZB03C13A	ALIF Trial, Large, 13mm, 8°	1
KZB03C15A	ALIF Trial, Large, 15mm, 8°	1
KZB03C17A	ALIF Trial, Large, 17mm, 8°	1
KZB03C19A	ALIF Trial, Large, 19mm, 8°	1
KZB03C21A	ALIF Trial, Large, 21mm, 8°	1

ALIF TRIAL, X-LARGE, 8°

Part Number	Description	Qty
KZB03D11A	ALIF Trial, X-Large, 11mm, 8°	1
KZB03D13A	ALIF Trial, X-Large, 13mm, 8°	1
KZB03D15A	ALIF Trial, X-Large, 15mm, 8°	1
KZB03D17A	ALIF Trial, X-Large, 17mm, 8°	1
KZB03D19A	ALIF Trial, X-Large, 19mm, 8°	1
KZB03D21A	ALIF Trial, X-Large, 21mm, 8°	1

ALIF TRIAL, SMALL, 15°

Part Number	Description	Qty
KZB03A11B	ALIF Trial, Small, 11mm, 15°	1
KZB03A13B	ALIF Trial, Small, 13mm, 15°	1
KZB03A15B	ALIF Trial, Small, 15mm, 15°	1
KZB03A17B	ALIF Trial, Small, 17mm, 15°	1
KZB03A19B	ALIF Trial, Small, 19mm, 15°	1
KZB03A21B	ALIF Trial, Small, 21mm, 15°	1

ALIF TRIAL, MEDIUM, 15°

Part Number	Description	Qty
KZB03B11B	ALIF Trial, Medium, 11mm, 15°	1
KZB03B13B	ALIF Trial, Medium, 13mm, 15°	1
KZB03B15B	ALIF Trial, Medium, 15mm, 15°	1
KZB03B17B	ALIF Trial, Medium, 17mm, 15°	1
KZB03B19B	ALIF Trial, Medium, 19mm, 15°	1
KZB03B21B	ALIF Trial, Medium, 21mm, 15°	1

ALIF TRIALS

ALIF TRIAL, LARGE, 15°

Part Number	Description	Qty
KZB03C11B	ALIF Trial, Large, 11mm, 15°	1
KZB03C13B	ALIF Trial, Large, 13mm, 15°	1
KZB03C15B	ALIF Trial, Large, 15mm, 15°	1
KZB03C17B	ALIF Trial, Large, 17mm, 15°	1
KZB03C19B	ALIF Trial, Large, 19mm, 15°	1
KZB03C21B	ALIF Trial, Large, 21mm, 15°	1

ALIF TRIAL, X-LARGE, 15°

Part Number	Description	Qty
KZB03D11B	ALIF Trial, X-Large, 11mm, 15°	1
KZB03D13B	ALIF Trial, X-Large, 13mm, 15°	1
KZB03D15B	ALIF Trial, X-Large, 15mm, 15°	1
KZB03D17B	ALIF Trial, X-Large, 17mm, 15°	1
KZB03D19B	ALIF Trial, X-Large, 19mm, 15°	1
KZB03D21B	ALIF Trial, X-Large, 21mm, 15°	1

ALIF TRIAL, MEDIUM, 20°

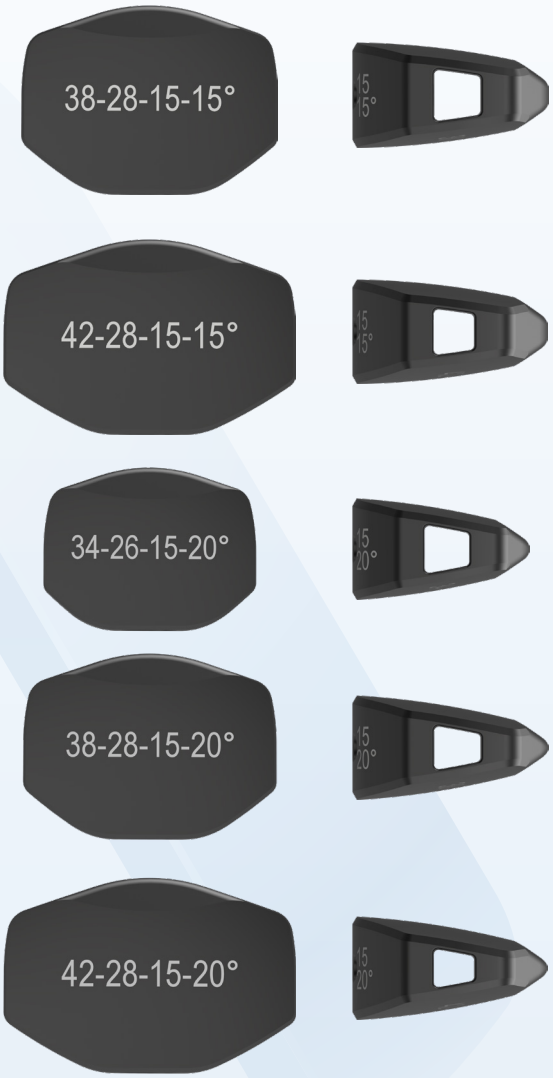
Part Number	Description	Qty
KZB03B15C	ALIF Trial, Medium, 15mm, 20°	1
KZB03B17C	ALIF Trial, Medium, 17mm, 20°	1
KZB03B19C	ALIF Trial, Medium, 19mm, 20°	1
KZB03B21C	ALIF Trial, Medium, 21mm, 20°	1

ALIF TRIAL, LARGE, 20°

Part Number	Description	Qty
KZB03C15C	ALIF Trial, Large, 15mm, 20°	1
KZB03C17C	ALIF Trial, Large, 17mm, 20°	1
KZB03C19C	ALIF Trial, Large, 19mm, 20°	1
KZB03C21C	ALIF Trial, Large, 21mm, 20°	1

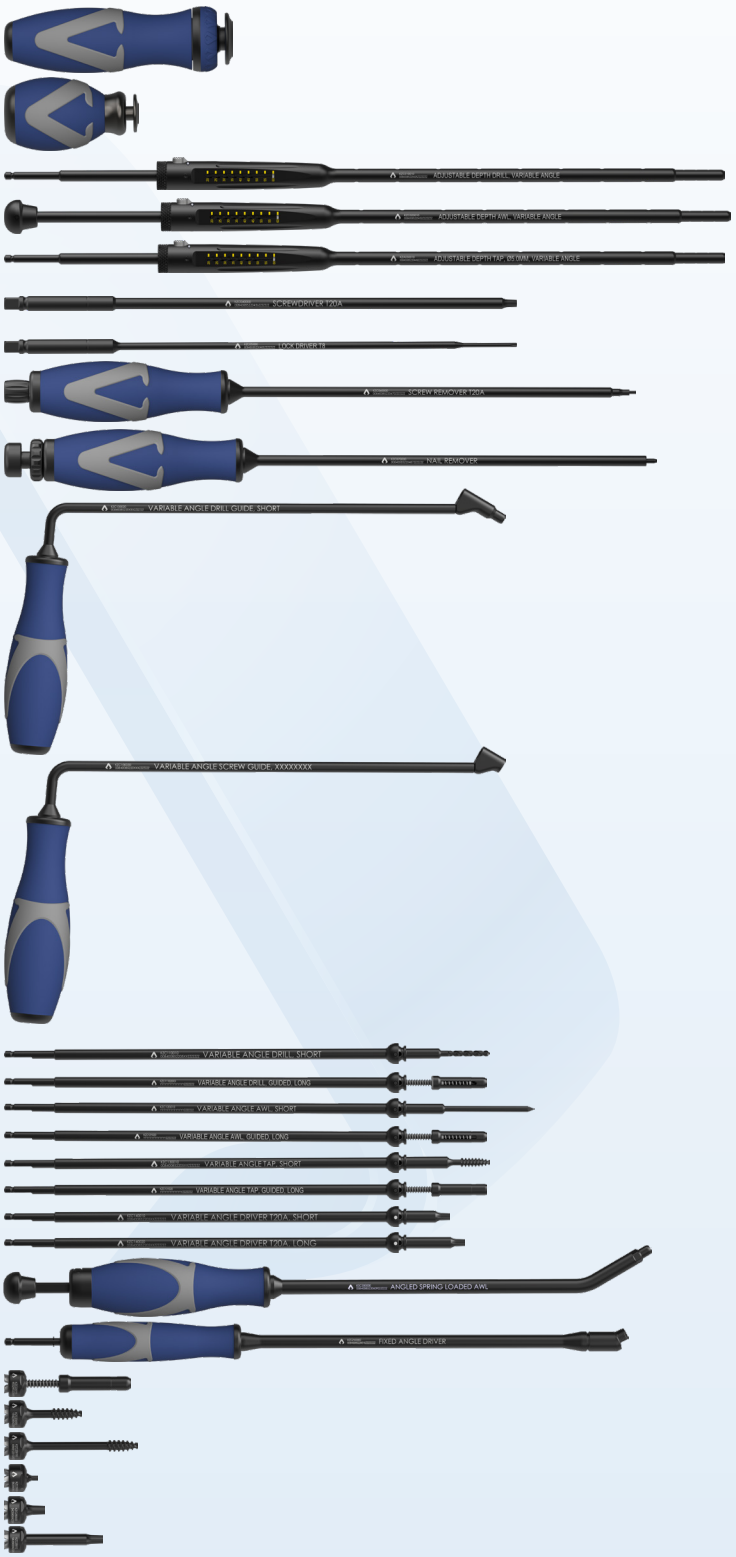
ALIF TRIAL, X-LARGE, 20°

Part Number	Description	Qty
KZB03D15C	ALIF Trial, X-Large, 15mm, 20°	1
KZB03D17C	ALIF Trial, X-Large, 17mm, 20°	1
KZB03D19C	ALIF Trial, X-Large, 19mm, 20°	1
KZB03D21C	ALIF Trial, X-Large, 21mm, 20°	1



ALIF FIXATION INSTRUMENTS

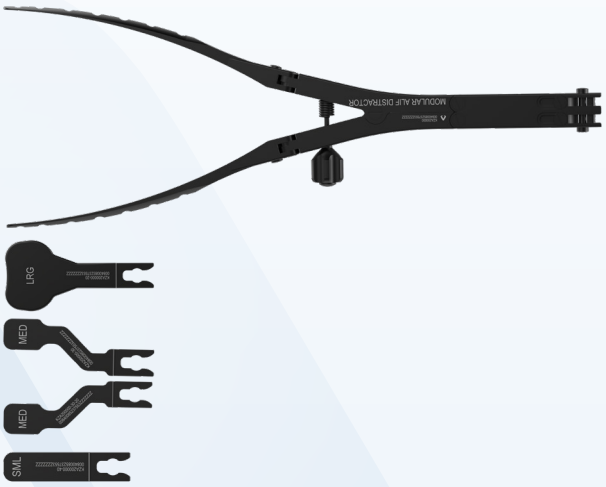
Part Number	Description	Qty
EAECDUBBZ	Axial, Large, 1/4" Square Ratchet	2
EDDEATAAZ	Egg Handle, AO	2
KZC010010	Adjustable Depth Drill	1
KZC020010	Adjustable Depth Awl	1
KZC030010	Adjustable Depth Tap, Ø5.0mm	1
KZC040000	Screwdriver, T20a	2
KZC050000	Lock Driver, T8	2
KZC060000	Screw Remover, T20a	1
KZC070000	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 ANTERIOR LUMBAR INTERBODY FUSION
OPTIONAL INSTRUMENTS

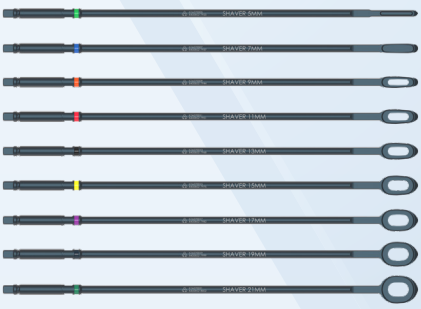
Modular ALIF Retractor (MAD-XXX)

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



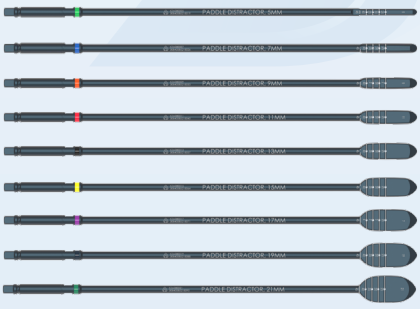
ALIF Shavers (ASHAVE-XXX)

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 anchors, 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) must be used with supplemental fixation (e.g. posterior fixation) that has been cleared by the FDA for use in the lumbar spine.

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.
6.1.15 Interference with radiographic, CT, and/or MR imaging because of the presence of the implants.
6.1.16 Graft donor site complications including pain, fracture, or wound healing problems.
6.1.17 Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
6.1.18 Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
6.1.19 Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
6.1.20 Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
6.1.21 Change in mental status.
6.1.22 Non-union (or pseudarthrosis). Delayed union. Mal-union.
6.1.23 Cessation of any potential growth of the operated portion of the spine. Loss of spinal mobility or function.
6.1.24 Inability to perform the activities of daily living.
6.1.25 Paralysis.
6.1.26 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 or migration 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 bginning 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.

9.4 The type of construct to be assembled for the case should be determined prior to bginning 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 AND DECONTAMINATION: Instruments of the EL CAPITAN SYSTEM are supplied clean and NOT STERILE, and must be sterilized prior to use

14.0 CLEANING: All instruments 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.

15.0 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.

16.0 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.

17.0 COMPANY INFORMATION

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

NOTES


ASTURA
MEDICAL