EL CAPITAN X

EXPANDABLE ANTERIOR LUMBAR SPACER

ASTURA MEDICAL

DESIGN RATIONALE

The El Capitan X Expandable Anterior Lumbar Interbody Fusion System is a comprehensive technology platform that provides a complete range of expandable anatomic spacers and fixation options with infinitely adjustable expansions in height and lordosis for a unique, patient-specific solution. The system's intuitive design offers the versatility to accommodate many implant options and expansive instrumentation that deliver a streamlined, efficient procedural sequence that addresses numerous variations of complex pathologies through multiple approaches.

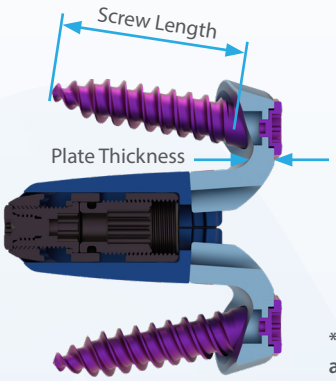
- ***EL CAPITAN X Expandable Spacers have independent expansion capability in height and lordosis to minimize insertion size while allowing controlled disc height restoration and optimized fit***
- ***EL CAPITAN X Expandable Spacers include either plated or non-plated options with standard or hyperlordotic implant options***
- ***Starting heights: 10, 11, 13, or 15mm***
- ***Max Lordosis: up to 30°***
- ***Ability to expand vertically up to 7.5mm for controlled disc height restoration and optimized fit for maximum intraoperative versatility***
- ***Footprint: 30x24mm, 34x26mm, 38x28mm, and 42x28mm***

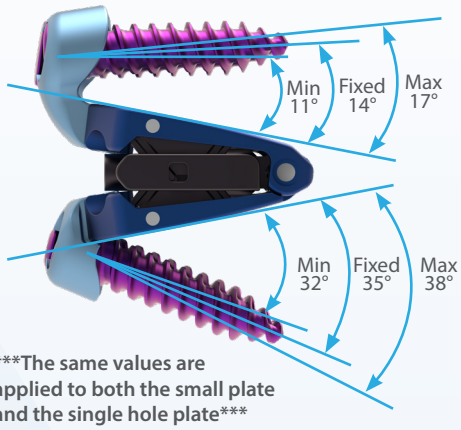
SPECIFICATIONS

SPACER SIZING			
TYPE	**FOOTPRINT (mm)**	**STARTING HEIGHT (mm)**	**STARTING LORDOSIS (DEG)**
Acid-Etched Titanium Spacer	30x24, 34x26, 38x28, 42x28	10, 11, 13, 15	0, 3, 8, 12

FIXATION TYPES AND SIZING			
TYPE	**CONSTRAINT**	**DIAMETERS (mm)**	**LENTGHS (mm)**
Self-Drilling Screws	Variable	5.0 or 5.5	20, 25, 30

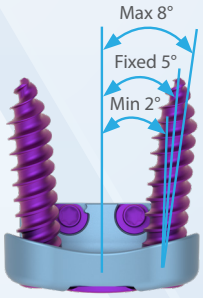
PLATE TYPES AND SIZING			
TYPE	**POINTS OF FIXATION**	**HEIGHT (mm)**	**THICKNESS (mm)**
Blank	0	Spacer Height	N/A
Single-Holed	1	10	3
Small	2	10	3
Tall	2	15	3



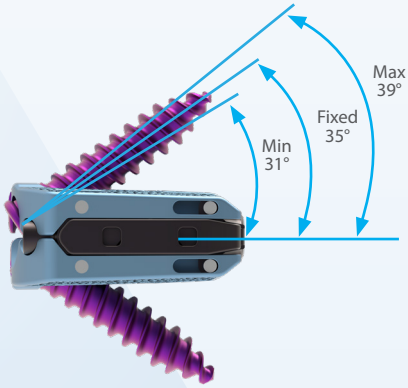


The same values are applied to both the small plate and the single hole plate

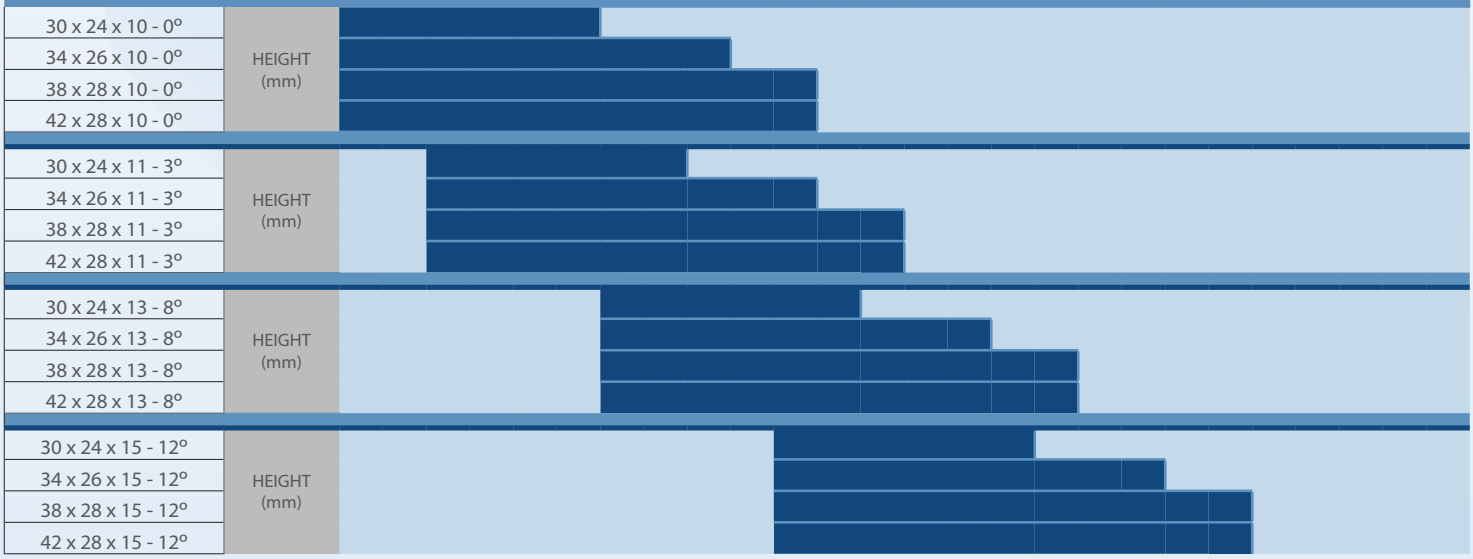
2-hole Small Plate



2-hole Tall Plate



FULLY ADJUSTABLE - PARALLEL EXPANSION CAPABILITIES



LORDOSIS CAPABILITIES
FULLY ADJUSTABLE & HYPERLORDOTIC

FULLY ADJUSTABLE - LORDOSIS CAPABILITIES

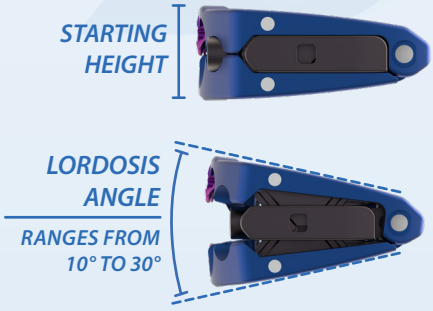
SIZE & STARTING HEIGHT (mm)	HEIGHT (mm)	10.0	10.5	11.0	11.5	12.0	12.5	13.0	13.5	14.0	14.5	15.0	15.5	16.0	16.5	17.0	17.5	18.0	18.5	19.0	19.5	20.0	20.5	21.0	21.5	22.0	22.5
30 x 24 x 10 - 0°	LORDOSIS	0	1.7	3.2	4.6	6.1	7.6	9.1	10.6	12.1	13.5																
34 x 26 x 10 - 0°		0	1.7	3.0	4.3	5.6	7.0	8.3	9.7	11.1	12.5	14.0	15.4	17.5													
38 x 28 x 10 - 0°		0	1.6	2.8	4.0	5.2	6.5	7.7	9.0	10.3	11.5	12.9	14.2	15.5	16.9	18.2	20.5										
42 x 28 x 10 - 0°		0	1.6	2.8	4.0	5.2	6.5	7.7	9.0	10.3	11.5	12.9	14.2	15.5	16.9	18.2	20.5										
30 x 24 x 11 - 3°	LORDOSIS			3.0	3.5	5.0	6.4	7.9	9.4	10.9	12.4	13.9	15.0														
34 x 26 x 11 - 3°				3.0	3.5	4.8	6.1	7.4	8.8	10.1	11.5	12.9	14.3	15.8	17.2	19.0											
38 x 28 x 11 - 3°				3.0	3.4	4.6	5.8	7.0	8.3	9.5	10.8	12.1	13.4	14.7	16.0	17.4	18.7	20.1	22.0								
42 x 28 x 11 - 3°				3.0	3.4	4.6	5.8	7.0	8.3	9.5	10.8	12.1	13.4	14.7	16.0	17.4	18.7	20.1	22.0								
30 x 24 x 13 - 8°	LORDOSIS							8.0	8.1	9.5	10.9	12.4	13.9	15.4	16.9	18.5	20.0										
34 x 26 x 13 - 8°								8.0	8.1	9.3	10.6	12.0	13.3	14.7	16.1	17.5	18.9	20.4	21.8	23.5							
38 x 28 x 13 - 8°								8.0	8.1	9.2	10.4	11.6	12.8	14.1	15.4	16.7	18.0	19.3	20.6	22.0	23.3	24.7	26.5				
42 x 28 x 13 - 8°								8.0	8.1	9.2	10.4	11.6	12.8	14.1	15.4	16.7	18.0	19.3	20.6	22.0	23.3	24.7	26.5				
30 x 24 x 15 - 12°	LORDOSIS											12.0	12.5	13.2	14.7	16.2	17.7	19.2	20.7	22.3	23.5						
34 x 26 x 15 - 12°												12.0	12.3	13.1	14.4	15.7	17.1	18.4	19.8	21.2	22.7	24.1	25.6	27.5			
38 x 28 x 15 - 12°												12.0	12.2	12.9	14.1	15.3	16.6	17.8	19.1	20.4	21.7	23.0	24.4	25.7	27.1	28.5	30.0
42 x 28 x 15 - 12°												12.0	12.2	12.9	14.1	15.3	16.6	17.8	19.1	20.4	21.7	23.0	24.4	25.7	27.1	28.5	30.0

HYPERLORDOTIC - LORDOSIS CAPABILITIES

SIZE (MM)	HEIGHT (mm)	10.0	10.5	11.0	11.5	12.0	12.5	13.0	13.5	14.0	14.5	15.0	15.5	16.0	16.5	17.0	17.5	18.0	18.5	19.0	19.5	20.0	20.5	21.0	21.5	22.0	22.5
30 x 24	LORDOSIS	12.0	13.4	14.7	16.1	17.5	18.9	20.3	21.7	23.1	24.5	25.9	27.3	28.7	30.0												
34 x 26		11.0	12.3	13.5	14.8	16.0	17.3	18.5	19.8	21.1	22.4	23.6	24.9	26.2	27.5	28.8	30.0										
38 x 28		10.0	11.2	12.3	13.5	14.6	15.8	16.9	18.1	19.3	20.4	21.6	22.8	24.0	25.1	26.3	27.5	29.0									
42 x 28		10.0	11.2	12.3	13.5	14.6	15.8	16.9	18.1	19.3	20.4	21.6	22.8	24.0	25.1	26.3	27.5	29.0									

FULLY ADJUSTABLE

HYPERLORDOTIC



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.

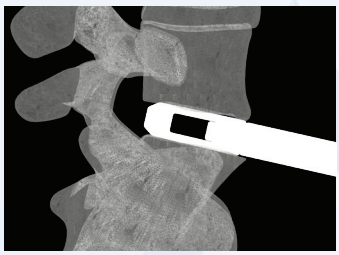
4.0 IMPLANT TRIALING ASSEMBLY AND INSERTION

4.1 Implant Trialing

4.1.1 Choose the appropriate footprint Trial (KZD1800XX). Attach the Trial to the Trial Inserter (KZD010000) 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. Fluoroscopy can be used to confirm the desired anatomic alignment.

4.1.3 Thread Slap Hammer Adapter (KZD210000) onto Slap Hammer (KZD150000) then attach the Slap Hammer to the proximal portion of the Trial Inserter to facilitate removal of the Trials from the disc space.



4.2 Screw Preparation

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

4.2.1.1 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.

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

4.2.1.3 Place the distal end of the Drill into the Spacer screw bore and advance the Drill until bottomed out (set depth above, mm).

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

4.2.1.5 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.

4.2.2 Variable Angle (Drill, Tap, Screw) **(with or without Inserter attached)**

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

4.2.2.2 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).

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

4.2.2.4 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.

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

4.2.3.1 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.

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

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

4.2.3.4 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.

4.2.4 Fixed Angle (Awl) (KZC200000) **(without Inserter attached)**

4.2.4.1 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 Implant Assembly (Plated Spacer - Optional)

4.3.1 Select the Spacer (Fully adjustable: KL00XXXXX, KK00XXXXX/Hyperlordotic: KQ00XXXXX, KP00XXXXX) that matches the chosen Trial. Select the Plate (KMA000000, KMB000000, KMC000000, KMD000000) which provides the desired approach and number of fixation points. Attach the Plate to the Spacer by aligning the interlocking grooves, then sliding the Plate down until it bottoms out.

4.3.2 Using the Plate Lock Driver (KZD020000), engage the driver tip into Plate Locking Cam and rotate clockwise until stopped.

4.3.3 If necessary, use the Plate Lock Driver (KZD020000) to remove the Plate by engaging the driver tip into the Plate Locking Cam and rotate counter clockwise until stopped.

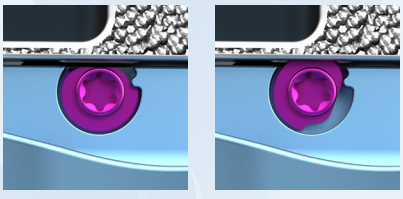
4.4 Implant Insertion and Expansion

4.4.1 Spacer Insertion

4.4.1.1 Align the Spacer to the Inserter (KZD030010, KZD030020 – Hyperlordotic) and thread the two proximal knobs until the implant is secure. The Hyperlordotic Inserter (KZD030020) drive shaft and proximal cap is color coded Gold for identification and is only to be used with a Hyperlordotic Spacer (KP00XXXXX, KQ00XXXXX).

4.4.1.2 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.

4.4.1.3 To increase implant depth following Inserter removal, locate Tamp (KZD110000) into threaded holes of Spacer, then impact using the Mallet (KZB110000) until the desired depth is achieved. Confirm anatomic alignment using fluoroscopy.



UNLOCKED LOCKED

4.4.2 Implant Expansion **(with Inserter attached)**

4.4.2.1 With the Spacer located in the disc space, assemble the selected height driver to the 30 in-lbs Torque Limiting Egg Handle (EDECGAAZH).

4.4.2.2 Height Driver (KZD070000)

4.3.2.2.1 Insert the gold Height Driver into the proximal end of the Inserter (KZD030010) and rotate in a clockwise direction to achieve simultaneous anterior and posterior height adjustment and counter clockwise to decrease height.

4.4.2.3 Anterior Height Driver (KZD060000)

4.3.2.3.1 Insert the black Anterior Height Driver into the proximal end of the Inserter and rotate in a clockwise direction to increase anterior height, and counter clockwise to decrease anterior height. Note: The Spacer is unable to adjust to a negative kyphotic angle.

4.4.2.4 Posterior Height Driver (KZD050000)

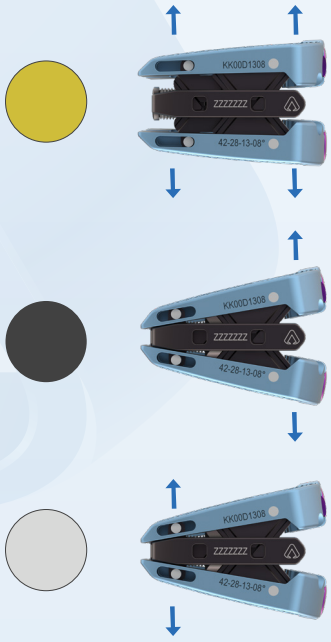
4.3.2.4.1 Insert the chrome Posterior Height Driver into the proximal end of the Inserter and rotate in a clockwise direction to increase posterior height, and counter clockwise to decrease posterior height. Note: The Spacer is unable to adjust to a negative kyphotic angle.

4.4.3 Hyperlordotic Implant Expansion **(with Inserter attached)**

4.3.3.1 With the Spacer located in the disc space, assemble the selected height driver to the 30 in-lbs Torque Limiting Egg Handle (EDECGAAZH).

4.3.3.2 Insert the black Anterior Height Driver (KZD060000) into the proximal end of the Hyperlordotic Inserter (KZD030020) and rotate in a clockwise direction until the desired height / lordosis is achieved. Turn counter clockwise to decrease height / lordosis

EXPANSION TYPE	DRIVER / PART NUMBER	COLOR
Vertical (Ant. & Post.)	A/P Driver / KZD070000	Gold
Anterior (Height/Lordosis)	Ant. Driver / KZD060000	Black
Posterior (Height/Lordosis)	Post. Driver / KZD050000	Chrome



4.3.4 Implant Expansion **(without Inserter attached)**

4.3.4.1 With the Spacer located in the disc space, assemble the selected height drive shaft to the 30 in-lbs Torque Limiting Egg Handle (EDECGAAZH).

4.3.4.2 Height Driver (KZD070000)

4.3.4.2.1 Insert the gold Height Drive Shaft into the Implants central bore and rotate in a clockwise direction to achieve simultaneous anterior and posterior height adjustment and counter clockwise to decrease height.

4.3.4.3 Anterior Height Drive Shaft (KZD100000)

4.3.4.3.1 Insert the black Anterior Height Drive Shaft into the Implants central bore and rotate in a clockwise direction to increase anterior height, and counter clockwise to decrease anterior height. Note: The Spacer is unable to adjust to a negative kyphotic angle.

4.3.4.4 Posterior Height Drive Shaft (KZD090000)

4.3.4.4.1 Insert the chrome Posterior Height Drive Shaft (KZD090000) into the Implants central bore and rotate in a clockwise direction to increase posterior height, and counter clockwise to decrease posterior height. Note: The Spacer is unable to adjust to a negative kyphotic angle.

4.3.5 Hyperlordotic Implant Expansion **(without Inserter attached)**

4.3.5.1 With the Spacer located in the disc space, assemble the black Anterior Height Drive Shaft (KZD100000) to the 30 in-lbs Torque Limiting Egg Handles (EDECGAAZH).

4.3.5.2 Insert the black Anterior Height Drive Shaft (KZD100000) into the Implants central bore and rotate in a clockwise direction until the desired height / lordosis is achieved. Turn counter clockwise to decrease height / lordosis.

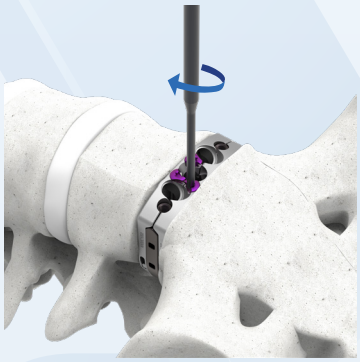
EXPANSION TYPE	DRIVER / PART NUMBER	COLOR
Vertical (Ant. & Post.)	A/P Drive Shaft / KZD080000	Gold
Anterior (Height/Lordosis)	Ant. Drive Shaft / KZD100000	Black
Posterior (Height/Lordosis)	Post. Drive Shaft / KZD090000	Chrome

4.3.7 Implant Locking

4.3.8.1 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.

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

* (Zero Plate and Half Plate Lower Cam (T8) - 180° (XXXXXXXX)
Full Plate Upper Cam (T20) - 180° (XXXXXXXX))



4.3.8 Intervertebral Graft Delivery

4.3.8.1 The Implant may be post filled with bone graft through the use of the Bone Graft Plunger (KZD120000), Funnel (KZD130000) and Tube (KZD140000).

4.3.8.2 Thread the Funnel and Tube together, then place bone graft material into the Funnel. Push the material through the Tube into the Implant using the Bone Graft Plunger.

4.3.9 Implant Removal

4.3.9.1 Screw Removal

4.3.9.1.1 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.

4.3.9.1.2 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.

4.3.9.2 Spacer Removal

4.3.9.2.1 Obtain the Inserter (KZD030010, KZD030020), then align the Implant to the inserter and thread the two proximal knobs until the Implant is secure.

4.3.9.2.2 Assemble the required height driver to collapse the Implant, to the 30 in-lbs Torque Limiting Egg Handles (EDECGAAZH). Insert the height driver into the proximal end of the Inserter and rotate in a counter clockwise direction.

4.3.9.2.3 Assemble the Slap Hammer (KZD150000) to the Inserter, then reverse impact until the Spacer is removed.

4.3.9.2.4 Thread the Inserter Adapter (KZD200000) onto the Slap Hammer (KZD150000) prior to use.

EL CAPITAN EXPANDABLE ALIF IMPLANT OFFERING

ALIF EXPANDABLE SPACER, STANDARD, NON-PLATED

Part Number	Description	Qty
KK00A1000	ALIF Expandable Spacer, Small, 10mm, 0°	2
KK00A1103	ALIF Expandable Spacer, Small, 11mm, 3°	2
KK00A1308	ALIF Expandable Spacer, Small, 13mm, 8°	2
KK00A1512	ALIF Expandable Spacer, Small, 15mm, 12°	1
KK00B1000	ALIF Expandable Spacer, Medium, 10mm, 0°	2
KK00B1103	ALIF Expandable Spacer, Medium, 11mm, 3°	2
KK00B1308	ALIF Expandable Spacer, Medium, 13mm, 8°	2
KK00B1512	ALIF Expandable Spacer, Medium, 15mm, 12°	1
KK00C1000	ALIF Expandable Spacer, Large, 10mm, 0°	2
KK00C1103	ALIF Expandable Spacer, Large, 11mm, 3°	2
KK00C1308	ALIF Expandable Spacer, Large, 13mm, 8°	2
KK00C1512	ALIF Expandable Spacer, Large, 15mm, 12°	1
KK00D1000	ALIF Expandable Spacer, Extra Large, 10mm, 0°	2
KK00D1103	ALIF Expandable Spacer, Extra Large, 11mm, 3°	2
KK00D1308	ALIF Expandable Spacer, Extra Large, 13mm, 8°	2
KK00D1512	ALIF Expandable Spacer, Extra Large, 15mm, 12°	1

ALIF EXPANDABLE SPACER, STANDARD, PLATED

Part Number	Description	Qty
KL00A1000	ALIF Expandable Spacer, Plated, Small, 10mm, 0°	2
KL00A1103	ALIF Expandable Spacer, Plated, Small, 11mm, 3°	2
KL00A1308	ALIF Expandable Spacer, Plated, Small, 13mm, 8°	2
KL00A1512	ALIF Expandable Spacer, Plated, Small, 15mm, 12°	1
KL00B1000	ALIF Expandable Spacer, Plated, Medium, 10mm, 0°	2
KL00B1103	ALIF Expandable Spacer, Plated, Medium, 11mm, 3°	2
KL00B1308	ALIF Expandable Spacer, Plated, Medium, 13mm, 8°	2
KL00B1512	ALIF Expandable Spacer, Plated, Medium, 15mm, 12°	1
KL00C1000	ALIF Expandable Spacer, Plated, Large, 10mm, 0°	2
KL00C1103	ALIF Expandable Spacer, Plated, Large, 11mm, 3°	2
KL00C1308	ALIF Expandable Spacer, Plated, Large, 13mm, 8°	2
KL00C1512	ALIF Expandable Spacer, Plated, Large, 15mm, 12°	1
KL00D1000	ALIF Expandable Spacer, Plated, Extra Large, 10mm, 0°	2
KL00D1103	ALIF Expandable Spacer, Plated, Extra Large, 11mm, 3°	2
KL00D1308	ALIF Expandable Spacer, Plated, Extra Large, 13mm, 8°	2
KL00D1512	ALIF Expandable Spacer, Plated, Extra Large, 15mm, 12°	1

EL CAPITAN EXPANDABLE ALIF IMPLANT OFFERING

ALIF EXPANDABLE SPACER, HYPERLORDOTIC, NON-PLATED

Part Number	Description	Qty
KP00A1012	ALIF Expandable Spacer, Hyperlordotic, Small, 10mm, 12°	1
KP00B1011	ALIF Expandable Spacer, Hyperlordotic, Medium, 10mm, 11°	1
KP00C1010	ALIF Expandable Spacer, Hyperlordotic, Large, 10mm, 10°	1
KP00D1010	ALIF Expandable Spacer, Hyperlordotic, Extra Large, 10mm, 10°	1

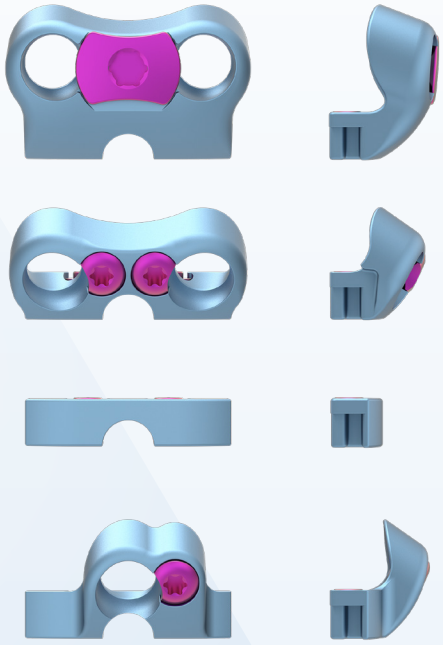
ALIF EXPANDABLE SPACER, HYPERLORDOTIC, PLATED

Part Number	Description	Qty
KQ00A1012	ALIF Expandable Spacer, Hyperlordotic, Plated, Small, 10mm, 12°	1
KQ00B1011	ALIF Expandable Spacer, Hyperlordotic, Plated, Medium, 10mm, 11°	1
KQ00C1010	ALIF Expandable Spacer, Hyperlordotic, Plated, Large, 10mm, 10°	1
KQ00D1010	ALIF Expandable Spacer, Hyperlordotic, Plated, Extra Large, 10mm, 10°	1

EL CAPITAN EXPANDABLE ALIF PLATE AND PLATE SCREW OFFERING

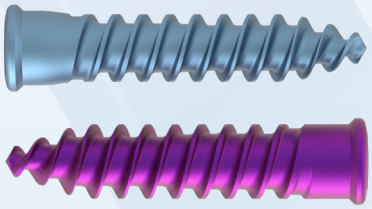
ALIF EXPANDABLE PLATE

Part Number	Description	Qty
KMA000000	ALIF Expandable, Tall Plate	6
KMB000000	ALIF Expandable, Small Plate	6
KMC000000	ALIF Expandable, Blank Plate	3
KMD000000	ALIF Expandable, Single Hole Plate	3



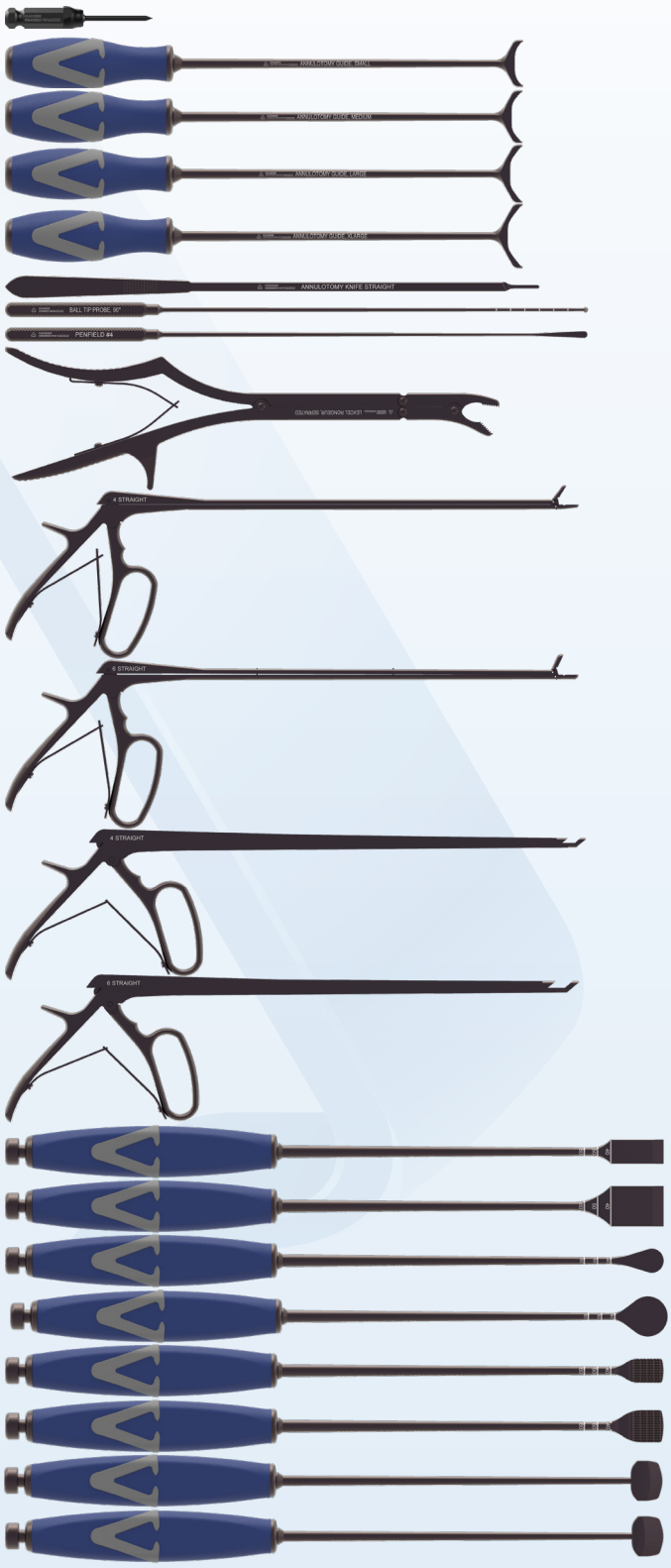
ALIF EXPANDABLE SCREWS, SELF-DRILLING

Part Number	Description	Qty
KNAB05020	ALIF Expandable Screws, Self-Drilling, 5.0mmx20mm	12
KNAB05025	ALIF Expandable Screws, Self-Drilling, 5.0mmx25mm	12
KNAB05030	ALIF Expandable Screws, Self-Drilling, 5.0mmx30mm	12
KNAB05520	ALIF Expandable Screws, Self-Drilling, 5.5mmx20mm	6
KNAB05525	ALIF Expandable Screws, Self-Drilling, 5.5mmx25mm	6
KNAB05530	ALIF Expandable Screws, Self-Drilling, 5.5mmx30mm	6



EL CAPITAN EXPANDABLE 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 EXPANDABLE ALIF 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

EL CAPITAN EXPANDABLE ALIF SPACER INSTRUMENTS

Part Number	Description	Qty
KZD010000	Expandable ALIF, Trial Inserter	2
KZD020000	Expandable ALIF, Plate Lock Driver	1
KZD030010	Expandable ALIF, Inserter	1
KZB110000	Mallet	1
KZD030020	Expandable ALIF, Inserter, Hyperlordotic	1
KZD050000	Expandable ALIF, Posterior Height Driver	1
KZD060000	Expandable ALIF, Anterior Height Driver	1
KZD070000	Expandable ALIF, Height Driver	1
KZD080000	Expandable ALIF, Height Drive Shaft	1
KZD090000	Expandable ALIF, Posterior Height Drive Shaft	1
KZD100000	Expandable ALIF, Anterior Height Drive Shaft	1
EDECGAAZH	Egg Torque, Inline, Bidirectional, 1/4SQ, 30in-lbs	2
KZD110000	Expandable ALIF, Tamp	1
KZD120000	Expandable ALIF, Bone Graft Funnel, Plunger	1
KZD130000	Expandable ALIF, Bone Graft Funnel, Body	1
KZD140000	Expandable ALIF, Bone Graft Funnel, Tube	1
KZD150000	Expandable ALIF Slap Hammer	1
KZD200000	Expandable ALIF Slap Hammer, Inserter Adapter	1
KZD210000	Expandable ALIF Slap Hammer, Adapter	1

EL CAPITAN EXPANDABLE ALIF RASPING TRIALS

ALIF EXPANDABLE RASPING TRIAL, SMALL

Part Number	Description	Qty
KZD1800AA	ALIF Expandable Rasping Trial, Small, 10mm, 0°	1
KZD1800AB	ALIF Expandable Rasping Trial, Small, 11mm, 3°	1
KZD1800AC	ALIF Expandable Rasping Trial, Small, 13mm, 8°	1
KZD1800AD	ALIF Expandable Rasping Trial, Small, 15mm, 12°	1

ALIF EXPANDABLE RASPING TRIAL, MEDIUM

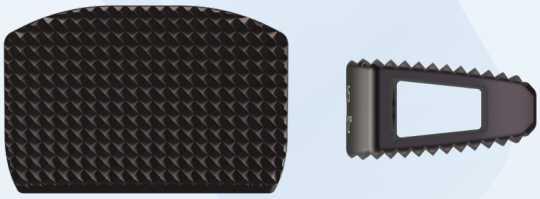
Part Number	Description	Qty
KZD1800BA	ALIF Expandable Rasping Trial, Medium, 10mm, 0°	1
KZD1800BB	ALIF Expandable Rasping Trial, Medium, 11mm, 3°	1
KZD1800BC	ALIF Expandable Rasping Trial, Medium, 13mm, 8°	1
KZD1800BD	ALIF Expandable Rasping Trial, Medium, 15mm, 12°	1

ALIF EXPANDABLE RASPING TRIAL, LARGE

Part Number	Description	Qty
KZD1800CA	ALIF Expandable Rasping Trial, Large, 10mm, 0°	1
KZD1800CB	ALIF Expandable Rasping Trial, Large, 11mm, 3°	1
KZD1800CC	ALIF Expandable Rasping Trial, Large, 13mm, 8°	1
KZD1800CD	ALIF Expandable Rasping Trial, Large, 15mm, 12°	1

ALIF EXPANDABLE RASPING TRIAL, EXTRA LARGE

Part Number	Description	Qty
KZD1800DA	ALIF Expandable Rasping Trial, Extra Large, 10mm, 0°	1
KZD1800DB	ALIF Expandable Rasping Trial, Extra Large, 11mm, 3°	1
KZD1800DC	ALIF Expandable Rasping Trial, Extra Large, 13mm, 8°	1
KZD1800DD	ALIF Expandable Rasping Trial, Extra Large, 15mm, 12°	1



ALIF EXPANDABLE RASPING TRIAL, HYPERLORDOTIC

Part Number	Description	Qty
KZD19000A	ALIF Expandable Rasping Trial, Hyperlordotic, Small	1
KZD19000B	ALIF Expandable Rasping Trial, Hyperlordotic, Medium	1
KZD19000C	ALIF Expandable Rasping Trial, Hyperlordotic, Large	1
KZD19000D	ALIF Expandable Rasping Trial, Hyperlordotic, Extra Large	1

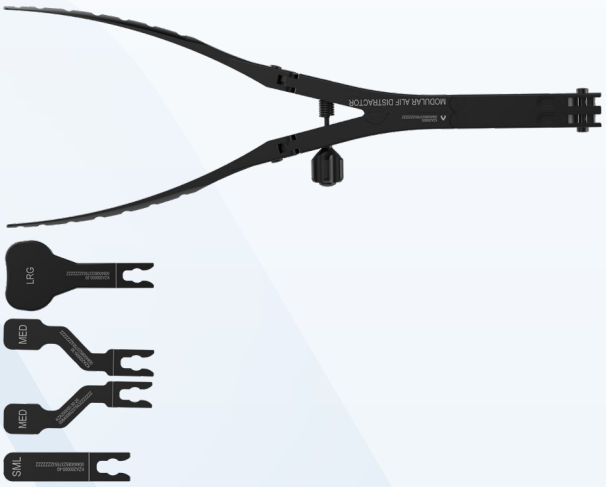
EXPANDABLE ALIF FIXATION INSTRUMENTS

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
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
GZD140000	Fixed Angled Driver Bit Socket	1

EL CAPITAN EXPANDABLE ALIF
OPTIONAL INSTRUMENTS

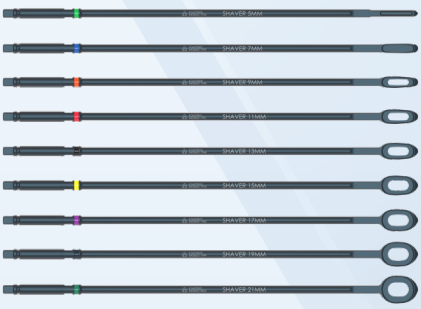
Modular ALIF Retractor (MAD-XXX)

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



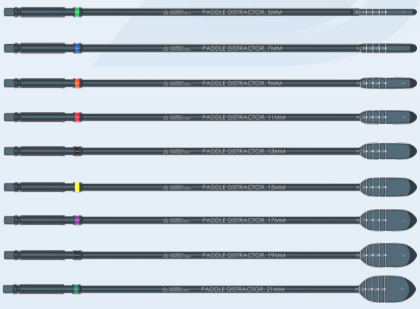
ALIF Shavers (ASHAVE-XXX)

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 X
EXPANDABLE ANTERIOR LUMBAR SPACER

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)), Cobalt Chrome (ASTM F1537).

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 pr ocedures 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 fusio n, 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.

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	270ºF(132ºC)	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.

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

NOTES

NOTES

NOTES


ASTURA
MEDICAL