SIRION

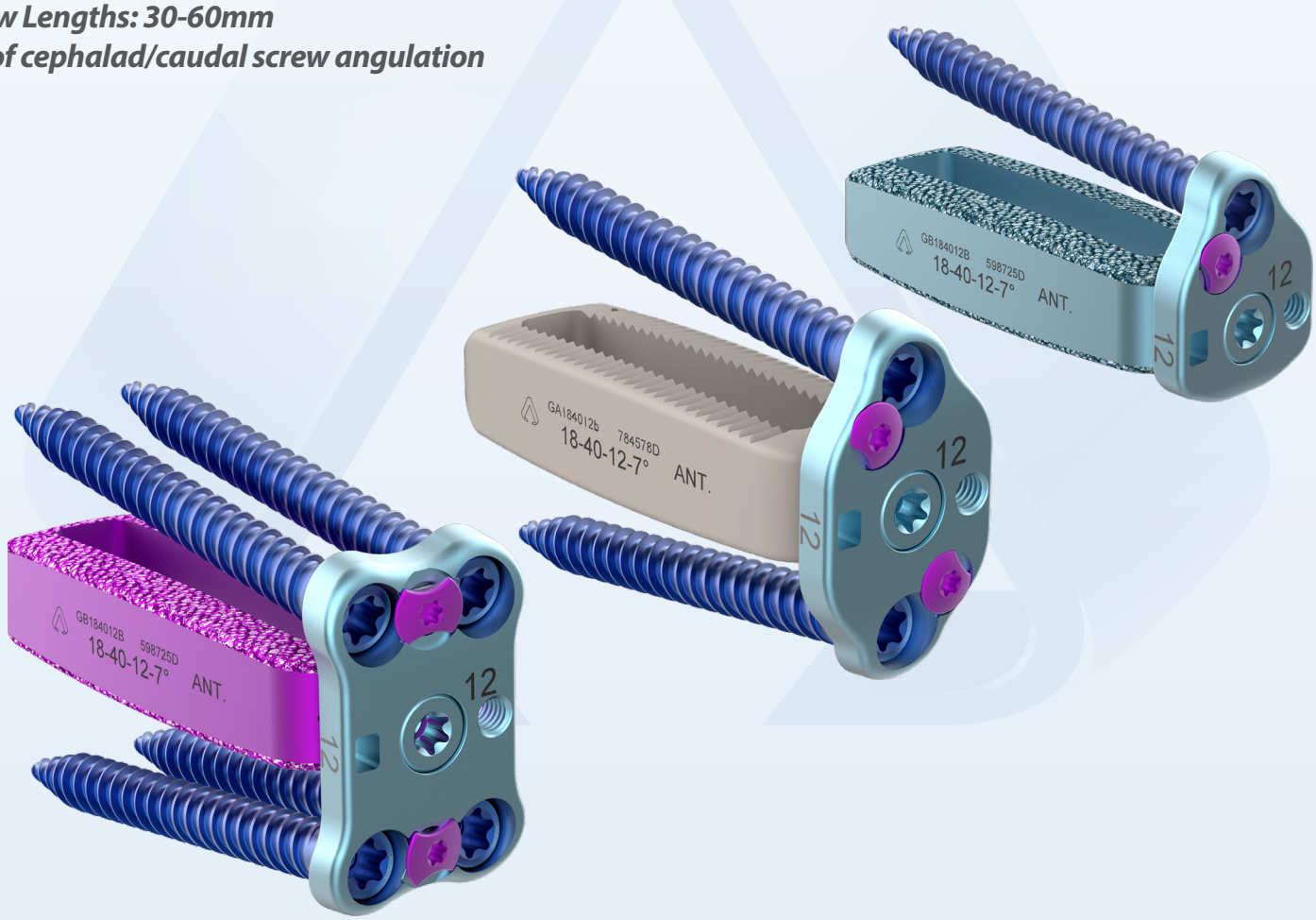
LATERAL LUMBAR INTERBODY FUSION

ASTURA MEDICAL

DESIGN RATIONALE

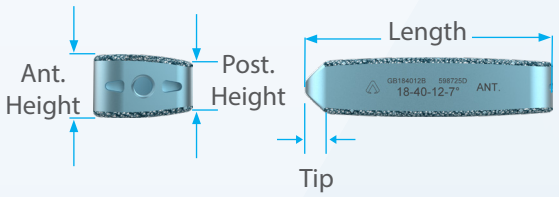
The SIRION Lateral Lumbar Interbody Fusion System by ASTURA MEDICAL is a comprehensive system that provides a complete range of anatomic spacers and fixation options for rigid lateral stabilization. The intuitive design of the system provides the versatility to accommodate a wide array of anatomical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

- ***All SIRION Spacers are available in Acid-Etched Titanium or HA PEEK***
- ***Interchangeable plate and interbody spacer options***
- ***One, Two, or Four Hole Plates***
- ***5.5 & 6.0mm Screws***
- ***Screw Lengths: 30-60mm***
- ***15° of cephalad/caudal screw angulation***



SPECIFICATIONS

SPACER SIZING						
	Width (mm)	Length (mm)	Tip (mm)	Ant. Heights (mm)	Post. Heights (mm)	Lordosis
Standard Spacer	18 or 22	45, 50, 55, 60	5	7,8,10,12,14,16		7° or 15°
Hyperlordotic Spacer	18 or 22	45, 50, 55, 60	5		2,4,6,8,10	20°, 25°, 30°



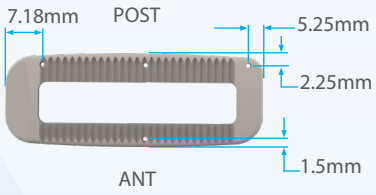
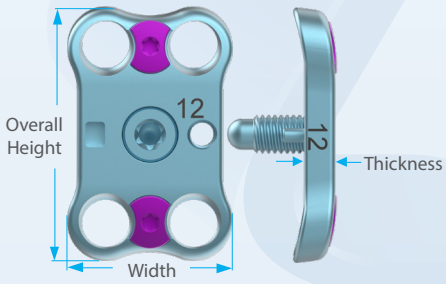
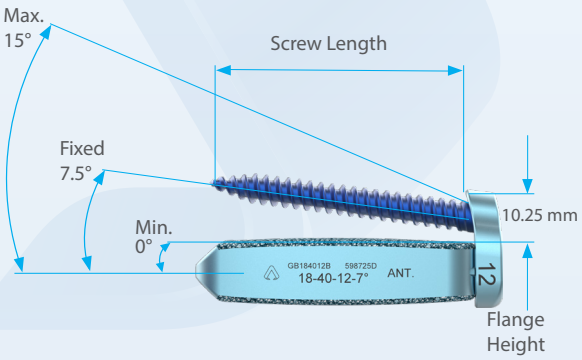


PLATE TYPES AND SIZING					
	Type	Plate Size (mm)	Overall Height (mm)	Width (mm)	Thickness (mm)
1 Hole	Attached	8, 10, 12, 14, 16, 18, 20	(8) 19.25, (10) 21.25, (12) 23.25, (14) 25.25, (16) 27.25, (18) 29.25, (20) 31.25	18.5	4
	Detached	7, 8, 10, 12, 14, 16, 18, 20	(7) 18.25, (8) 19.25, (10) 21.25, (12) 23.25, (14) 25.25, (16) 27.25, (18) 29.25, (20) 31.25		
2 Hole	Attached	8, 10, 12, 14, 16, 18, 20	(8) 28.51, (10) 30.51, (12) 32.51, (14) 34.51, (16) 36.51, (18) 38.51, (20) 40.51	18.5	4
	Detached	7, 8, 10, 12, 14, 16, 18, 20	(7) 27.51, (8) 28.51, (10) 30.51, (12) 32.51, (14) 34.51, (16) 36.51, (18) 38.51, (20) 40.51		
4 Hole	Attached	8, 10, 12, 14, 16, 18, 20	(8) 28.51, (10) 30.51, (12) 32.51, (14) 34.51, (16) 36.51, (18) 38.51, (20) 40.51	21	4
	Detached	7, 8, 10, 12, 14, 16, 18, 20	(7) 27.51, (8) 28.51, (10) 30.51, (12) 32.51, (14) 34.51, (16) 36.51, (18) 38.51, (20) 40.51		





SCREW TYPES AND SIZING			
	Constraint	Diameters (mm)	Lengths (mm)
Self-Drilling	Variable	5.5 or 6.0	30-60

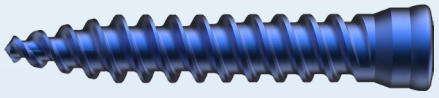
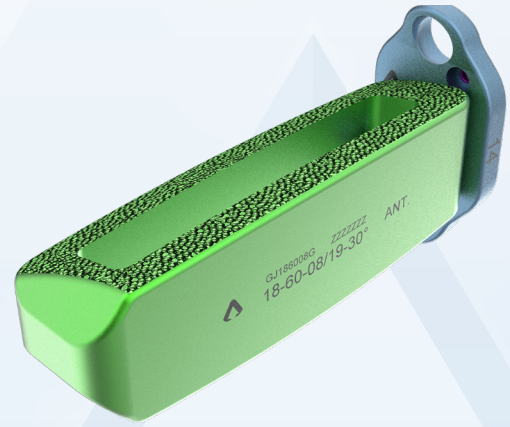


PLATE TYPES AND SIZING

Spacer Size	Plate Size		
	1 HOLE	2 HOLE	4 HOLE
18 x 45 x 07 x 7°	07*	07*	07*
18 x 45 x 08 x 7°	08	08	08
18 x 45 x 10 x 7°	10	10	10
18 x 45 x 12 x 7°	12	12	12
18 x 45 x 14 x 7°	14	14	14
18 x 45 x 16 x 7°	16	16	16
18 x 50 x 07 x 7°	07*	07*	07*
18 x 50 x 08 x 7°	08	08	08
18 x 50 x 10 x 7°	10	10	10
18 x 50 x 12 x 7°	12	12	12
18 x 50 x 14 x 7°	14	14	14
18 x 50 x 16 x 7°	16	16	16
18 x 55 x 07 x 7°	07*	07*	07*
18 x 55 x 08 x 7°	08	08	08
18 x 55 x 10 x 7°	10	10	10
18 x 55 x 12 x 7°	12	12	12
18 x 55 x 14 x 7°	14	14	14
18 x 55 x 16 x 7°	16	16	16
18 x 60 x 07 x 7°	07*	07*	07*
18 x 60 x 08 x 7°	08	08	08
18 x 60 x 10 x 7°	10	10	10
18 x 60 x 12 x 7°	12	12	12
18 x 60 x 14 x 7°	14	14	14
18 x 60 x 16 x 7°	16	16	16
18 x 45 x 7 x 12°	07*	07*	07*
18 x 45 x 8 x 15°	08	08	08
18 x 45 x 10 x 15°	10	10	10
18 x 45 x 12 x 15°	12	12	12
18 x 45 x 14 x 15°	14	14	14
18 x 45 x 16 x 15°	16	16	16
18 x 50 x 7 x 12°	07*	07*	07*
18 x 50 x 8 x 15°	08	08	08
18 x 50 x 10 x 15°	10	10	10
18 x 50 x 12 x 15°	12	12	12
18 x 50 x 14 x 15°	14	14	14
18 x 50 x 16 x 15°	16	16	16
18 x 55 x 7 x 12°	07*	07*	07*
18 x 55 x 8 x 15°	08	08	08
18 x 55 x 10 x 15°	10	10	10
18 x 55 x 12 x 15°	12	12	12
18 x 55 x 14 x 15°	14	14	14
18 x 55 x 16 x 15°	16	16	16
18 x 60 x 7 x 12°	07*	07*	07*
18 x 60 x 8 x 15°	08	08	08
18 x 60 x 10 x 15°	10	10	10
18 x 60 x 12 x 15°	12	12	12
18 x 60 x 14 x 15°	14	14	14
18 x 60 x 16 x 15°	16	16	16

* Detached Plate Only



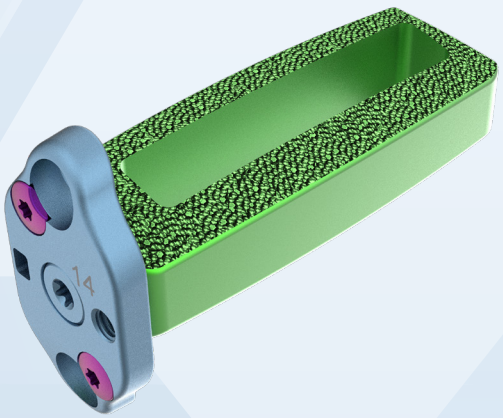


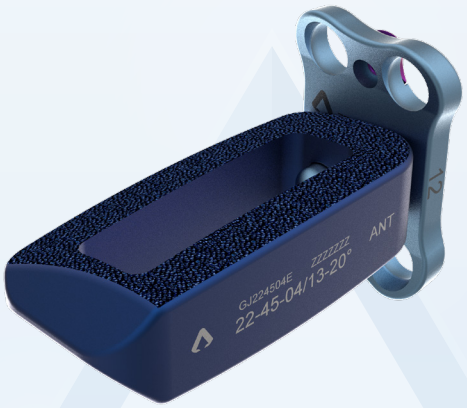
PLATE TYPES AND SIZING

Spacer Size	Plate Size		
	1 HOLE	2 HOLE	4 HOLE
18 x 45 x 02/10 x 20°	08	08	10
18 x 45 x 02/11 x 25°	10	10	18
18 x 45 x 02/13 x 30°	10	10	12
18 x 45 x 04/12 x 20°	08	08	10
18 x 45 x 04/13 x 25°	10	10	12
18 x 45 x 04/15 x 30°	10	10	12
18 x 45 x 06/14 x 20°	10	10	12
18 x 45 x 06/15 x 25°	12	12	14
18 x 45 x 06/17 x 30°	12	12	14
18 x 45 x 08/16 x 20°	12	12	14
18 x 45 x 08/17 x 25°	14	14	16
18 x 45 x 08/19 x 30°	14	14	16
18 x 45 x 10/18 x 20°	14	14	16
18 x 45 x 10/19 x 25°	16	16	18
18 x 45 x 10/21 x 30°	16	16	18
18 x 50 x 02/10 x 20°	08	08	10
18 x 50 x 02/11 x 25°	10	10	18
18 x 50 x 02/13 x 30°	10	10	12
18 x 50 x 04/12 x 20°	08	08	10
18 x 50 x 04/13 x 25°	10	10	12
18 x 50 x 04/15 x 30°	10	10	12
18 x 50 x 06/14 x 20°	10	10	12
18 x 50 x 06/15 x 25°	12	12	14
18 x 50 x 06/17 x 30°	12	12	14
18 x 50 x 08/16 x 20°	12	12	14
18 x 50 x 08/17 x 25°	14	14	16
18 x 50 x 08/19 x 30°	14	14	16
18 x 50 x 10/18 x 20°	14	14	16
18 x 50 x 10/19 x 25°	16	16	18
18 x 50 x 10/21 x 30°	16	16	18
18 x 55 x 02/10 x 20°	08	08	10
18 x 55 x 02/11 x 25°	10	10	18
18 x 55 x 02/13 x 30°	10	10	18
18 x 55 x 04/12 x 20°	08	08	10
18 x 55 x 04/13 x 25°	10	10	12
18 x 55 x 04/15 x 30°	10	10	12
18 x 55 x 06/14 x 20°	10	10	12
18 x 55 x 06/15 x 25°	12	12	14
18 x 55 x 06/17 x 30°	12	12	14
18 x 55 x 08/16 x 20°	12	12	14
18 x 55 x 08/17 x 25°	14	14	16
18 x 55 x 08/19 x 30°	14	14	16
18 x 55 x 10/18 x 20°	14	14	16
18 x 55 x 10/19 x 25°	16	16	18
18 x 55 x 10/21 x 30°	16	16	18
18 x 60 x 02/10 x 20°	08	08	10
18 x 60 x 02/11 x 25°	10	10	18
18 x 60 x 02/13 x 30°	10	10	18
18 x 60 x 04/12 x 20°	08	08	10
18 x 60 x 04/13 x 25°	10	10	12
18 x 60 x 04/15 x 30°	10	10	12
18 x 60 x 06/14 x 20°	10	10	12
18 x 60 x 06/15 x 25°	12	12	14
18 x 60 x 06/17 x 30°	12	12	14
18 x 60 x 08/16 x 20°	12	12	14
18 x 60 x 08/17 x 25°	14	14	16
18 x 60 x 08/19 x 30°	14	14	16
18 x 60 x 10/18 x 20°	14	14	16
18 x 60 x 10/19 x 25°	16	16	18
18 x 60 x 10/21 x 30°	16	16	18

PLATE TYPES AND SIZING

Spacer Size	Plate Size		
	1 HOLE	2 HOLE	4 HOLE
22 x 45 x 07 x 7°	07*	07*	07*
22 x 45 x 08 x 7°	08	08	08
22 x 45 x 10 x 7°	10	10	10
22 x 45 x 12 x 7°	12	12	12
22 x 45 x 14 x 7°	14	14	14
22 x 45 x 16 x 7°	16	16	16
22 x 50 x 07 x 7°	07*	07*	07*
22 x 50 x 08 x 7°	08	08	08
22 x 50 x 10 x 7°	10	10	10
22 x 50 x 12 x 7°	12	12	12
22 x 50 x 14 x 7°	14	14	14
22 x 50 x 16 x 7°	16	16	16
22 x 55 x 07 x 7°	07*	07*	07*
22 x 55 x 08 x 7°	08	08	08
22 x 55 x 10 x 7°	10	10	10
22 x 55 x 12 x 7°	12	12	12
22 x 55 x 14 x 7°	14	14	14
22 x 55 x 16 x 7°	16	16	16
22 x 60 x 07 x 7°	07*	07*	07*
22 x 60 x 08 x 7°	08	08	08
22 x 60 x 10 x 7°	10	10	10
22 x 60 x 12 x 7°	12	12	12
22 x 60 x 14 x 7°	14	14	14
22 x 60 x 16 x 7°	16	16	16
22 x 45 x 7 x 12°	07*	07*	07*
22 x 45 x 8 x 15°	08	08	08
22 x 45 x 10 x 15°	10	10	10
22 x 45 x 12 x 15°	12	12	12
22 x 45 x 14 x 15°	14	14	14
22 x 45 x 16 x 15°	16	16	16
22 x 50 x 7 x 12°	07*	07*	07*
22 x 50 x 8 x 15°	08	08	08
22 x 50 x 10 x 15°	10	10	10
22 x 50 x 12 x 15°	12	12	12
22 x 50 x 14 x 15°	14	14	14
22 x 50 x 16 x 15°	16	16	16
22 x 55 x 7 x 12°	07*	07*	07*
22 x 55 x 8 x 15°	08	08	08
22 x 55 x 10 x 15°	10	10	10
22 x 55 x 12 x 15°	12	12	12
22 x 55 x 14 x 15°	14	14	14
22 x 55 x 16 x 15°	16	16	16
22 x 60 x 7 x 12°	07*	07*	07*
22 x 60 x 8 x 15°	08	08	08
22 x 60 x 10 x 15°	10	10	10
22 x 60 x 12 x 15°	12	12	12
22 x 60 x 14 x 15°	14	14	14
22 x 60 x 16 x 15°	16	16	16

* Detached Plate Only



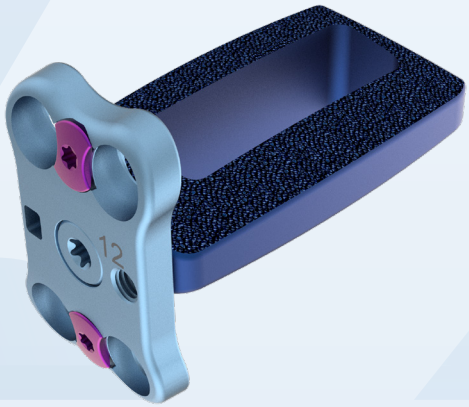


PLATE TYPES AND SIZING

Spacer Size	Plate Size		
	1 HOLE	2 HOLE	4 HOLE
22 x 45 x 02/11 x 20°	10	10	10
22 x 45 x 02/13 x 25°	10	10	12
22 x 45 x 02/15 x 30°	10	10	12
22 x 45 x 04/13 x 20°	10	10	12
22 x 45 x 04/15 x 25°	12	12	14
22 x 45 x 04/17 x 30°	12	12	14
22 x 45 x 06/15 x 20°	12	12	14
22 x 45 x 06/17 x 25°	14	14	16
22 x 45 x 06/19 x 30°	14	14	16
22 x 45 x 08/17 x 20°	14	14	16
22 x 45 x 08/19 x 25°	16	16	18
22 x 45 x 08/21 x 30°	16	16	18
22 x 45 x 10/19 x 20°	16	16	18
22 x 45 x 10/21 x 25°	18	18	20
22 x 45 x 10/23 x 30°	18	18	20
22 x 50 x 02/11 x 20°	10	10	10
22 x 50 x 02/13 x 25°	10	10	12
22 x 50 x 02/15 x 30°	10	10	12
22 x 50 x 04/13 x 20°	10	10	12
22 x 50 x 04/15 x 25°	12	12	14
22 x 50 x 04/17 x 30°	12	12	14
22 x 50 x 06/15 x 20°	12	12	14
22 x 50 x 06/17 x 25°	14	14	16
22 x 50 x 06/19 x 30°	14	14	16
22 x 50 x 08/17 x 20°	14	14	16
22 x 50 x 08/19 x 25°	16	16	18
22 x 50 x 08/21 x 30°	16	16	18
22 x 50 x 10/19 x 20°	16	16	18
22 x 50 x 10/21 x 25°	18	18	20
22 x 50 x 10/23 x 30°	18	18	20
22 x 55 x 02/11 x 20°	10	10	10
22 x 55 x 02/13 x 25°	10	10	12
22 x 55 x 02/15 x 30°	10	10	12
22 x 55 x 04/13 x 20°	10	10	12
22 x 55 x 04/15 x 25°	12	12	14
22 x 55 x 04/17 x 30°	12	12	14
22 x 55 x 06/15 x 20°	12	12	14
22 x 55 x 06/17 x 25°	14	14	16
22 x 55 x 06/19 x 30°	14	14	16
22 x 55 x 08/17 x 20°	14	14	16
22 x 55 x 08/19 x 25°	16	16	18
22 x 55 x 08/21 x 30°	16	16	18
22 x 55 x 10/19 x 20°	16	16	18
22 x 55 x 10/21 x 25°	18	18	20
22 x 55 x 10/23 x 30°	18	18	20
22 x 60 x 02/11 x 20°	10	10	10
22 x 60 x 02/13 x 25°	10	10	12
22 x 60 x 02/15 x 30°	10	10	12
22 x 60 x 04/13 x 20°	10	10	12
22 x 60 x 04/15 x 25°	12	12	14
22 x 60 x 04/17 x 30°	12	12	14
22 x 60 x 06/15 x 20°	12	12	14
22 x 60 x 06/17 x 25°	14	14	16
22 x 60 x 06/19 x 30°	14	14	16
22 x 60 x 08/17 x 20°	14	14	16
22 x 60 x 08/19 x 25°	16	16	18
22 x 60 x 08/21 x 30°	16	16	18
22 x 60 x 10/19 x 20°	16	16	18
22 x 60 x 10/21 x 25°	18	18	20
22 x 60 x 10/23 x 30°	18	18	20

1.0 PATIENT POSITIONING

1.1 Position the patient using the preferred lateral decubitus approach.

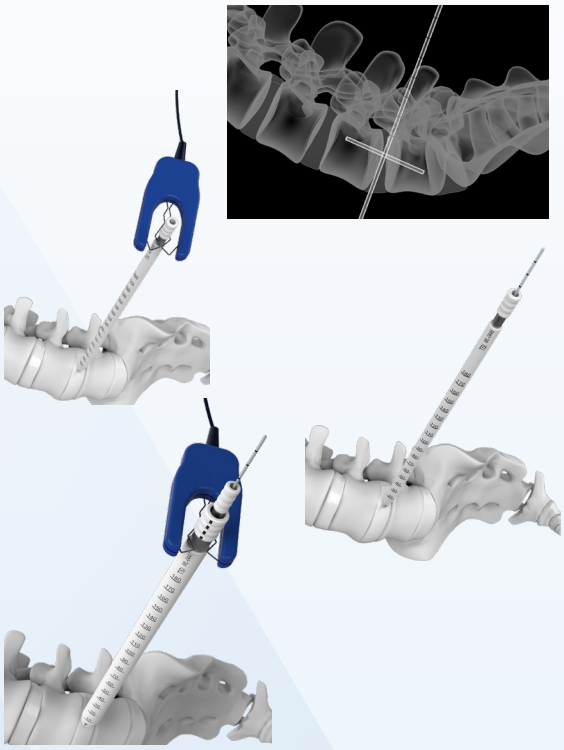
2.0 ACCESS

2.1 Using fluoroscopy, place the Incision Locater (GZA020000) over the surgical level, centered over the indicated disc space. Use a surgical marking pen to mark the desired skin incision.

2.2 Attach the Stimulating Clip (302775-200) onto the 8mm Dilator (ML-0440S), then guide the 8mm Dilator through the incision down to the disc space. Use fluoroscopic imaging to confirm location. To maintain distance from the x-ray field while imaging, grip the Dilator with the Dilator Holder (GZA050000).

2.3 Guide the Blunt Tip Guidewire (GZA030000) through the 8mm Dilator down to the disc space. Using fluoroscopic imaging to confirm location, penetrate the disc space using the Guidewire.

2.4 Disconnect the Stimulating Clip from the 8mm Dilator, then attach the Stimulating Clip to the 13mm Dilator ML-0440S. Repeat the advancing technique as described above. If using 22mm Blades (GZA11XXXX), continue to dilate using the18mm and 22mm Dilator (ML-0441S, ML-0449S).



3.0 RETRACTOR ASSEMBLY / OPERATING INSTRUCTIONS

3.1 Thread the distal end of the Retractor Handle (GZA130000) into the distal docking location located on the Retractor (GZA060000), then securely tighten. Additional torque can be applied by using the Retractor Driver (GZA140000).

3.2 Choose the blade length based on the depth markings identified on the Dilator.

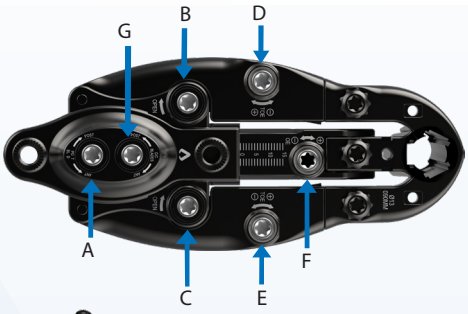
3.3 Clip the Posterior Blade (GZA08XXXX) onto the Retractor posterior arm, then use the Retractor Driver to thread the blade bolt into the posterior arm. Securely tighten, then confirm engagement by giving the blade a light tug.

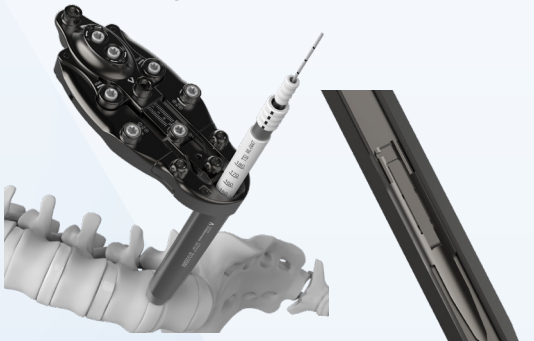
3.4 Clip the Cranial/Caudal Blades (GZA07XXXX) onto the Retractor toe arms, then use the Retractor Driver to thread the blade bolt into the toe arm. Securely tighten, then confirm engagement by giving the blade a light tug.

3.5 Visually ensure that the blades are aligned and closed. If not, adjust the blade opening and blade toe by inserting the Retractor Driver (GZA140000) into the following adjustment sites. Turning the Retractor Driver in a clockwise direction distracts/opens the specific adjustment site. Turning the Retractor Driver in a counter-clockwise direction retracts/closes the specific adjustment site.

- 3.5.1 A: Posterior Blade
- 3.5.2 B: Cranial Blade
- 3.5.3 C: Caudal Blade
- 3.5.4 D: Cranial Toe
- 3.5.5 E: Caudal Toe
- 3.5.6 F: Posterior Blade Toe
- 3.5.7 G: Cranial/Caudal Blades (Anterior)

3.6 Pre-loading of the Posterior Blade Shim (GZA2300XX) into the Posterior Blade is achievable prior to Retractor insertion. Follow the steps listed in Section 5, Retractor Stabilization, for Posterior Blade Shim assembly into the Posterior Blade.





4.0 RETRACTOR INSERTION

4.1 Slide the Retractor assembly over the 13mm Dilator (ML-0441S), then dock it on the disc / vertebral body. Use fluoroscopy to confirm location.

4.2 The Retractor Handle (GZA130000) may need to be removed to assemble the Table Fixation Arm (GZA150000) to the Retractor.

4.3 If desired, the Disc Shim can be deployed into the disc space with the Dilators in place using the Shim Tamp (GZA300000). Refer to Section 5.0 for further detail.

4.4 Locate the Table Fixation Clamp (5.750-N-VE) on the table rail.

4.5 Insert the Table Fixation Arm (GZA150000) into the Table Fixation Clamp, then provisionally tighten.

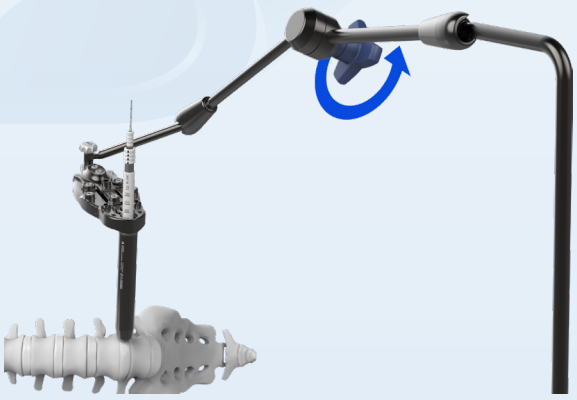
4.6 Turn the large knob on the Table Fixation Arm in a counter-clockwise direction to unlock movement, then thread the distal end of the Table Fixation Arm into the proximal docking location located on the Retractor. Additional torque can be applied by using the Retractor Driver (GZA140000).

4.7 Turn the large knob on the Table Fixation Arm in a clockwise direction to lock the movement.

4.8 Connect the Fiber Optic Cable to the light source using one of the provided Light Source Adapters, then attach the Bifurcated Surgical Illuminator (GZA160002) to the Fiber Optic Cable.

4.9 Insert the Bifurcated Surgical Illuminator into the desired blade channels.

4.10 Stimulate the exposed area with the Ball Tip Stimulating Probe (302430-000-200) to ensure the surgical field is free of neural elements.



5.0 RETRACTOR STABILIZATION

5.1 For increased Retractor (GZA060000) stability, utilize a Posterior Blade Shim (GZA2300XX).

5.1.1 Position the lever of the Shim Inserter (GZA220000) to "Unlocked", then assemble the Posterior Blade Shim into the Shim Inserter and lock by positioning the lever of the Shim Inserter to "Locked".

5.1.2 With the Posterior Blade Shim assembled to the Shim Inserter (GZA220000), insert the Posterior Blade Shim into the Posterior Blade channel, then position within the disc space. Use fluoroscopic imaging to confirm positioning.

5.1.3 Position Shim Inserter lever to "Unlocked" to release the Posterior Blade Shim.

5.1.4 If the Posterior Blade Shim was pre-loaded into the Posterior Blade (GZA0800XX) prior to Retractor Insertion, use the Shim Tamp (GZA300000) to position the Posterior Blade Shim in the disc space.

5.1.4.1 Turn the knob in the "OUT" direction to protrude out the lifter slide.

5.1.4.2 Insert the Shim Tamp into the Posterior Blade channel, then position the Posterior Blade Shim within the disc space. Use fluoroscopic imaging to confirm positioning.

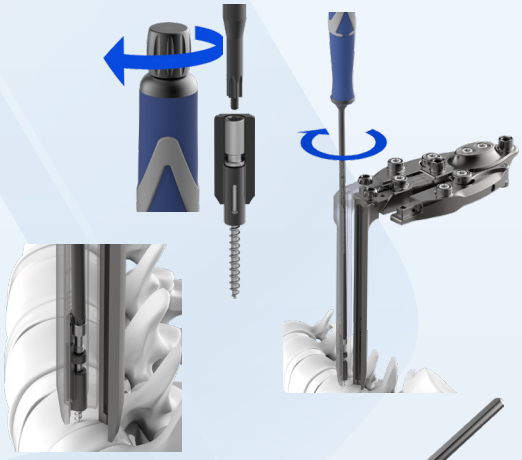
5.1.4.3 Turn the knob in the "IN" direction to retract the lifter side and disengage the Posterior Blade Shim. Remove the Shim Tamp from the Posterior Blade channel.

5.2 For Retractor fixation to the vertebral body, utilize the Threaded Bone Pin Shim (GZA270000).

5.2.1 Insert the T20 Threaded Bone Pin Driver (GZA280000) into the Threaded Bone Pin Shim, then turn the proximal knob in a clockwise direction to thread ably engage with the screw. Confirm engagement by giving the Threaded Bone Pin Shim a light tug.

5.2.2 Insert the Threaded Bone Pin Shim into the Cranial and/or Caudal Blade channel. Drive the Threaded Bone Pin Shim into the vertebral body by turning the T20 Threaded Bone Pin Driver clockwise. Use fluoroscopic imaging to confirm positioning. Turn the T20 Theareded Bone Pin driver knob counter-clockwise to disengage the driver from the Threaded Bon Pin Shim.

5.2.2.1 If toeing of the Cranial/Caudal Blades is required, remove the Threaded Bone Pin Shim before toeing. Refer to section 14, Closure, for shim removal.



6.0 ANTERIOR BLADE OPTION

6.1 Anterior Blades (GZA0900XX) can be used to create a barrier during removal of Anterior Longitudinal Ligament (ALL). The Anterior Blades can only be utilized after the Cranial/Caudal Blades have been opened to allow the Anterior Blade to fit between them.

6.1.1 Choose the appropriatesize Anterior Blade Mount (Narrow / Wide) (GZA1000XX), then attach it to the Cranial and Caudal Blades by inserting the pegs of the Anterior Blade Mount into the Cranial and Caudal Blade holes.

6.1.2 Choose the appropriate size and length Anterior Blade (Long 8mm, Long 12mm, Short 8mm, Short 12mm), then ensure the locking knob is unlocked by turning it in a counter-clockwise direction. Position the locking knob toward the top of the blade before use.

6.1.3 Insert the Anterior Blade into the working space, then position it up against the Anterior Blade Mount. Once in position, slide the locking knob down and engage the Anterior Blade Mount.

6.1.4 To lock the Anterior Blade position, thread the locking knob in a clockwise direction until finger tight.

7.0 DISC PREPARATION

7.1 Use a combination of the following instruments for access and preparation of the vertebral endplates:

7.1.1 Push/Pull Penfield (GZB0400XX) or Woodson (GZB050000) for dissection of the surgical site.

7.1.2 Suction (GZB030010) to clear fluid and debris from the surgical site.

7.1.3 Annulotomy Knife (GZB060000) to create the incision.

7.1.4 Straight and Angled (High & Low Offset) Instruments

7.1.4.1 Pituitary (GZB11XXXX) to remove disc material from the disc space.

7.1.4.2 Kerrison (GZB12SZXX) to assist in removing osteophytes or bone that prevents access to the disc space.

7.1.4.3 Box Cutter (GZB24XXXX) to release the ipsilateral or contralateral annulus.

7.1.4.4 Cobb (GZB09XXXX) to assist in removing cartilaginous endplates and/or release the annulus.

7.1.4.5 Curettes (GZB13XXX / GZB15XXXX) and Rasps (GZB16XXXX) to complete the endplate preparation.

7.1.5 Endplate Distractors (GZC025XXXX) can be used to mobilize and increase disc height during the discectomy process.

7.1.5.1 Depth indications can be visualized under fluoroscopic imaging and may be used as a guide to determining the implant length. The grooves/holes are located at 40, 45, 50, and 55mm from the tip. The end of the Distractor is 60mm.

7.1.7 Attach the Slap Hammer (GZC090000) to the proximal portion of the instrument to facilitate removal.

8.0 IMPLANT TRIALING, ASSEMBLY, AND INSERTION

8.1 Spacer Trialing

8.1.1 Choose the appropriate size Trial (GZC01XXXX), then attach the Trial to a 1/4" SQ. quick-connect handle. Confirm engagement by giving the trial a light tug.

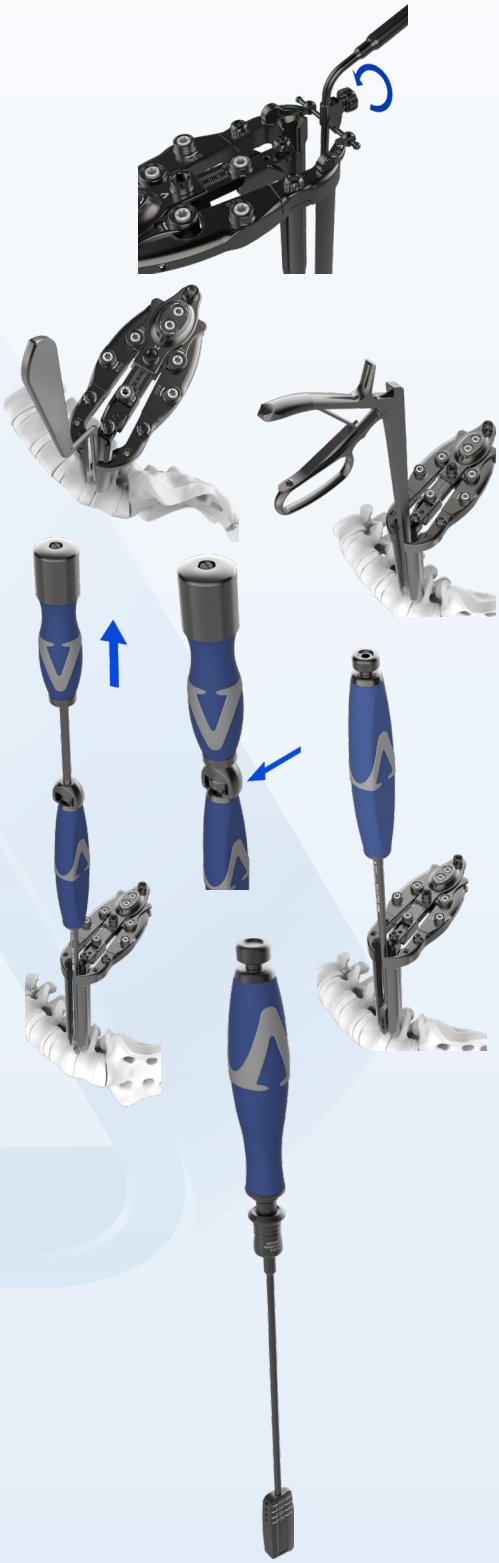
8.1.2 Start with a Trial height less than the disc space height, then increase the Trial height until the desired fitment is achieved.

8.1.2.1 Depth indications can be visualized under fluoroscopic imaging and may be used as a guide to determining the implant length. The holes are located at 40, 45, 50, and 55mm from the tip. The end of the Trial is 60mm.

8.1.3 Attach the Slap Hammer to the proximal portion of the handle to facilitate removal of the Trial from the disc space.

8.2 Spacer Insertion

8.2.1 Attach the Inserter (GZC040000) to a 1/4" SQ. quick-connect handle. Confirm engagement by giving the inserter a light tug.



8.2.2 Select the Spacer that matches the best fitting Trial, then thread the Spacer onto the Inserter by turning the knob in a clockwise direction until the instrument is flush with the Spacer. Confirm engagement by giving the Spacer a light tug. The 7mm Inserter (GZC040007) must be used when using a 7mm height Spacer.

8.2.2.1 For an angled approach, utilize the Angled Inserter (GZC0400A0).

8.2.2.2 For an angled approach using a 7mm Spacer, utilize the 7mm Angled Inserter (GZC0400A7).

8.2.3 Pack the selected Spacer with morselized bone graft material.

8.2.4 Insert the distal end of the Graft Retention Shims (GZC060000) into the surgical site, then locate within the disc space.

8.2.5 Spread the Graft Retention Shims to allow passage of the Spacer and Inserter. Place the tip of the Spacer between the Graft Retention Shims, then slide down until it is against the opening of the disc space.

8.2.5.1 When using a lordotic Spacer, confirm the "Anterior" identified on the Spacer is facing anterior during insertion.

8.2.6 While monitoring the insertion under fluoroscopic imaging, tap the Inserter using the Mallet (GZC080000) to locate the Spacer within the disc space.

8.2.7 Remove the Inserter from the Spacer by turning the Inserter knob in a counter-clockwise direction while pressing and holding the spring loaded button.

8.2.8 Removal of the Graft Retention Shims can be facilitated with the use of the Slap Hammer.

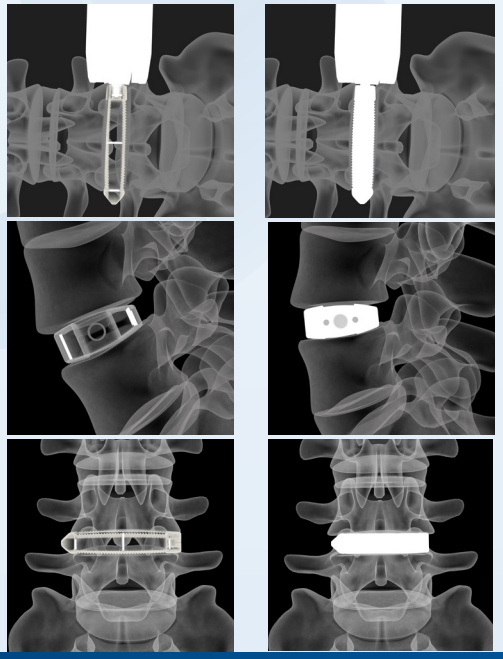
8.2.9 Utilize the Tamp (GZC070000) or Angled Tamp (GZC120000) if final positioning of the Spacer is not achieved with the Inserter attached.

9.0 RADIOGRAPHIC VERIFICATION

9.1 Proper placement of the Spacer is achieved when the primary body (minus the nose) is centered across the disc space on an A/P fluoroscopic view and between the anterior third and middle third of the disc space on a lateral fluoroscopic view.

9.1.1 HA PEEK Spacer: Radiographically, Spacer placement can be confirmed on a lateral view with the three vertical markers along the posterior edge aligned. Spacer placement on an A/P view can be confirmed with the two outer markers establishing the boundaries of the spacer and alignment of the two midline markers establishing orientation.

9.1.1.1 When a Plate is used with a Spacer, the Plate must rest against the vertebral body.



10.0 PLATE FIXATION

10.1 Plate to Spacer Assembly

10.1.1 Select the Spacer that matches the best fitting Trial. Select the desired Plate type (1 hole, 2 hole, or 4 hole) (1 hole plates are non-load bearing) and corresponding height to that of the chosen Spacer. (Refer to Spacer/Plate Size Selection Chart)

10.1.2 Thread the Plate onto the Plate Inserter (GZC040020) by turning the knob in a clockwise direction until the instrument is flush with the Plate.

10.1.2.1 For an angled approach, utilize the Angled Plate Inserter (GZC040030).

10.1.3 Attach the 15 in-lbs Torque Limiting Egg Handle to the Plate Inserter Torque Driver T15, then insert the driver into the Plate Inserter opening and engage the Plate Bolt. Confirm engagement by rotating the handle, then the Plate Bolt should rotate the same.

10.1.4 Position the Plate Bolt in the threaded hole of the Spacer and align the Plate peg with the Spacer alignment hole. Thread the Plate Bolt into the Spacer, then final tighten. Final tightening is achieved when the Torque Limiting Handle reaches 15 in-lbs and produces an audible click.

10.2 Plate Spacer Insertion

10.2.1 Attach the Plate Inserter to a 1/4" SQ. quick-connect handle. Confirm engagement by giving the inserter a light tug.

10.2.2 Pack the selected Spacer with morselized bone graft material.

10.2.3 Place the tip of the Spacer against the opening of the disc space. While monitoring the insertion using fluoroscopic imaging, tap the Inserter using the Mallet to locate the Spacer within the disc space.

10.2.4 Graft Retention Shims are not recommended for use when inserting a Plate-Spacer combo.

10.2.5 When using a lordotic Spacer, confirm the ANT (Anterior) identified on the Spacer is facing anterior during insertion.

10.2.6 Remove the Inserter from the Plate by turning the Inserter knob in a counter clockwise direction while pressing and holding the spring loaded button.

10.3 Plate Insertion (Post Spacer Insertion)

10.3.1 Attach the Plate Inserter to a 1/4 SQ. quick-connect handle. Confirm engagement by giving the inserter a light tug.

10.3.1.1 For an angled approach, utilize the Angled Plate Inserter.

10.3.2 Thread the Plate onto the Plate inserter by turning the knob in a clockwise direction until the instrument is flush with the Plate.

10.3.3 Attach Plate to Spacer

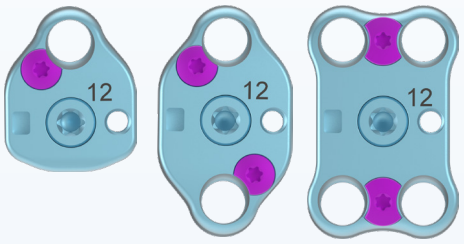
10.3.3.1 Attach the Plate Inserter Torque Driver T15 to the Torque Limiting Handle (EDECGAAZB), then insert the distal end of the driver into the central access hole of the Plate Inserter and engage with the Plate Bolt. Confirm engagement by rotating the handle. The Plate Bolt should rotate the same.

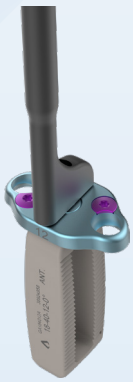
10.3.3.2 Insert the Plate into the surgical site, then locate the Plate Bolt with the Spacer threaded hole. Turn the Torque Limiting Egg handle in a clockwise direction to engage the Plate to the Spacer. The Plate alignment peg must locate into the Spacer pocket. Use flouroscopy to insure the Plate is flush with the Spacer before final torque.

10.3.3.3 Final tightening is achieved when the Torque Limiting Handle reaches 15 in-lbs. and produces an audible click.

10.3.4 Detached Plate

10.3.4.1 Insert the Plate into the surgical site then locate the Plate centered over the Spacer. See below for selecting the Screw Preparation options.





11.0 SCREW PREPARATION

11.1 Adjustable Drill

11.1.1 Set the Adjustable Drill (GZD020010) to the desired depth by pressing the locking button while threading the knurled knob in or out.

11.1.2 Attach the AO Egg Handle (EDDEATAAZ) or power drill to the Adjustable Drill, then locate the tip in the desired Plate screw hole and advance while rotating the handle in a clockwise direction. Confirm the depth and trajectory using fluoroscopy.

11.2 Adjustable Awl

11.2.1 Set the Adjustable Awl (GZD030010) to the desired depth by pressing the locking button while threading the knurled knob in or out.

11.2.2 Locate the Adjustable Awl tip in the desired plate screw hole, then advance by impacting the proximal impact cap using the Mallet. Confirm depth and trajectory using fluoroscopy.

11.3 Adjustable Tap

11.3.1 Set the Adjustable Tap 5.5mm (GZD040050) to the desired depth by pressing the locking button while threading the knurled knob in or out.

11.3.2 Attach the AO Egg Handle to the Adjustable Tap, then locate the Adjustable Tap tip in the desired plate screw hole. Then advance while rotating the handle in a clockwise direction. Confirm depth and trajectory using fluoroscopy.

11.4 Angled Drill

11.4.1 Assemble the 20mm Fixed Angle Drill (GZD020020) Bit to the distal end of the Fixed Angled Driver (GZD090000) by threading together.

11.4.2 Attach the AO Egg Handle or power drill to the proximal end of the Fixed Angled Driver.

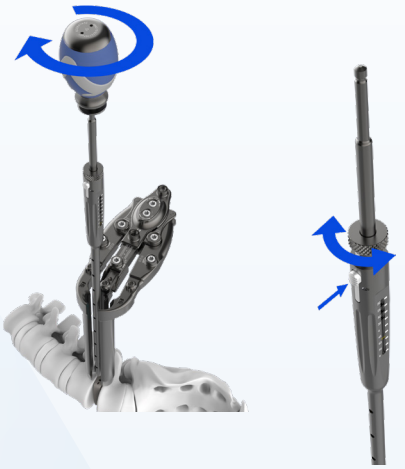
11.5 Angled Tap

11.5.1 Assemble the Fixed Angle Tap Bit (GZD110050) to the distal end of the Fixed Angled Driver (GZD090000) by threading together.

11.6 Attach the AO Egg Handle to the proximal end of the Fixed Angled Driver.

11.7 Angled Awl

11.7.1 Locate the Angled Awl tip in the desired plate screw hole, then advance to the desired depth. Confirm depth and trajectory using fluoroscopy.



12.0 SCREW INSERTION

12.1 Straight Screw Driver

12.1.1 Assemble the Axial ¼" Sq. Ratcheting Handle (EAECDUBBZ) to the T25 Screwdriver (GZD050000) by inserting the proximal end of the T25 Screwdriver into the distal end of the handle. Confirm engagement by giving the driver a light tug.

12.1.2 Insert the distal end of the T25 Screwdriver into the Screw (GDDABXXXX), then apply downward force. The driver will stick into the Screw head. Confirm the Screw is properly attached to the driver by lightly tugging on the Screw.

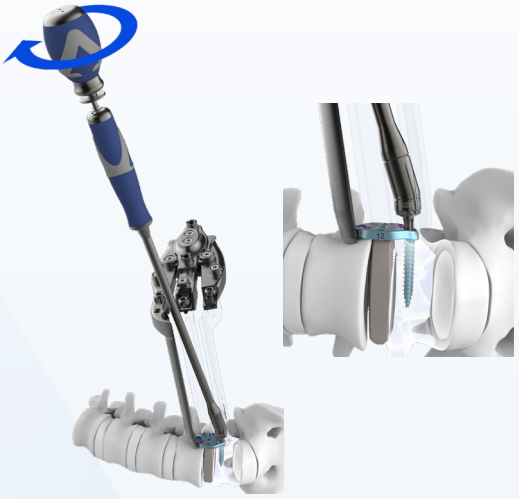
12.2 Angled Screw Driver

12.2.1 Assemble the T25 Fixed Angle Screwdriver Bit (GZD120010) to the distal end of the Fixed Angled Driver by threading together.

12.2.2 Attach the AO Egg Handle (EDDEATAAZ) to the proximal end of the Fixed Angled Driver.

12.2.3 Insert the distal end of the T25 Fixed Angle Screw Driver Bit into the Screw, then apply downward force. The driver will stick into the Screw head. Confirm the Screw is properly attached to the driver by lightly tugging on the Screw.

12.3 Insert the Screw (GDDAXXXXX) into the prepared hole, then rotate clockwise until the head of the Screw engages with the plate screw hole. Use fluoroscopy to ensure appropriate Screw placement.



13.0 PLATE LOCKING

13.1 Assemble the Axial 1/4" SQ. Ratcheting handle to the T8 Lockdriver (GZD070000) by inserting the proximal end of the driver into the distal end of the handle. Confirm engagement by giving the driver a light tug. Insert the tip of the T8 Lockdriver (GZD070000) into the mating feature within the Plate locking mechanism, then rotate 90°. Visually verify that all Screws are covered by the locking mechanism.

13.2 For an angled approach, assemble the T8 Lockdriver Bit (GZD120020) to the distal end of the Fixed Angled Driver by threading together.

13.3 Attach the AO Egg Handle to the proximal end of the Fixed Angled Driver.

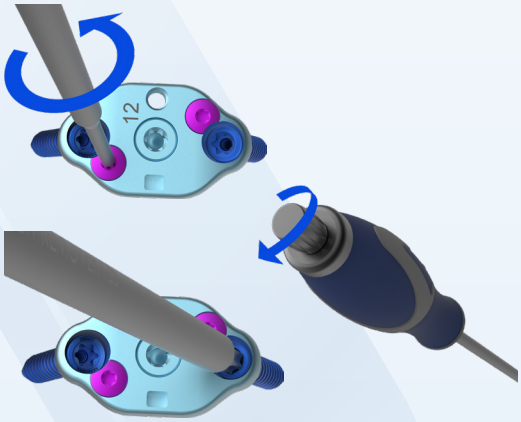
13.4 Approved supplemental fixation is required with use of the Sirion Lateral Interbody System.

15.0 CLOSURE

15.1 Remove the Bifurcated Surgical Illuminator from the Blade.
15.2 Utilize the Shim Inserter to remove the Posterior Blade Shim and any Blade Extension Shims.
15.3 Utilize the T20 Threaded Bone Pin Driver to remove the Threaded Bone Pin Shim.
15.4 Unthread the Anterior Blade knob in a counter-clockwise direction, then press the knob to remove the Anterior Blade.
15.5 Remove the Anterior Blade Attachment.
15.6 Return the Retractor Blade toe to the zero position by turning the toe adjustment sites in a counter-clockwise direction.
15.7 Retract the Posterior and Cranial/Caudal Blades by turning the adjustment sites in a counter-clockwise direction.
15.8 Remove the Table Fixation Arm by loosening the large knob, then unthread the distal knob attached to the Retractor in a counter-clockwise direction.
15.9 Close the wound using standard closure techniques.

16.0 REVISION/REMOVAL

16.1 Insert the tip of the T8 Lockdriver into the mating feature within the Plate locking mechanism, then rotate 90°.
16.2 Insert the T25 Screw Remover Driver (GZD060000) into the head of the Screw. Once coupled to the Screw, rotate the knob on the proximal portion of the T25 Screw Remover Driver clockwise until resistance is achieved. Rotate the Screw Remover Driver counter-clockwise until the Screw is removed from the Plate. Repeat for all remaining screws.



16.3 Once all Screws have been removed, attach the Inserter or Angled Inserter to a 1/4" SQ. quick-connect handle with a slap hammer cap, then assemble the inserter to the Plate or Spacer and use the Slap Hammer to remove the Spacer and Plate.

SIRION LATERAL LUMBAR INTERBODY FUSION HA PEEK OFFERING

LLIF HA PEEK SPACERS

Part Number	Description	Qty
GA184507B	LLIF Spacer, HA PEEK, 18mm x 45mm x 07mm x 7°, Non-Sterile	1
GA184508B	LLIF Spacer, HA PEEK, 18mm x 45mm x 08mm x 7°, Non-Sterile	2
GA184510B	LLIF Spacer, HA PEEK, 18mm x 45mm x 10mm x 7°, Non-Sterile	2
GA184512B	LLIF Spacer, HA PEEK, 18mm x 45mm x 12mm x 7°, Non-Sterile	2
GA184514B	LLIF Spacer, HA PEEK, 18mm x 45mm x 14mm x 7°, Non-Sterile	2
GA184516B	LLIF Spacer, HA PEEK, 18mm x 45mm x 16mm x 7°, Non-Sterile	1
GA185007B	LLIF Spacer, HA PEEK, 18mm x 50mm x 07mm x 7°, Non-Sterile	1
GA185008B	LLIF Spacer, HA PEEK, 18mm x 50mm x 08mm x 7°, Non-Sterile	2
GA185010B	LLIF Spacer, HA PEEK, 18mm x 50mm x 10mm x 7°, Non-Sterile	2
GA185012B	LLIF Spacer, HA PEEK, 18mm x 50mm x 12mm x 7°, Non-Sterile	2
GA185014B	LLIF Spacer, HA PEEK, 18mm x 50mm x 14mm x 7°, Non-Sterile	2
GA185016B	LLIF Spacer, HA PEEK, 18mm x 50mm x 16mm x 7°, Non-Sterile	1
GA185507B	LLIF Spacer, HA PEEK, 18mm x 55mm x 07mm x 7°, Non-Sterile	1
GA185508B	LLIF Spacer, HA PEEK, 18mm x 55mm x 08mm x 7°, Non-Sterile	2
GA185510B	LLIF Spacer, HA PEEK, 18mm x 55mm x 10mm x 7°, Non-Sterile	2
GA185512B	LLIF Spacer, HA PEEK, 18mm x 55mm x 12mm x 7°, Non-Sterile	2
GA185514B	LLIF Spacer, HA PEEK, 18mm x 55mm x 14mm x 7°, Non-Sterile	2
GA185516B	LLIF Spacer, HA PEEK, 18mm x 55mm x 16mm x 7°, Non-Sterile	1
GA186007B	LLIF Spacer, HA PEEK, 18mm x 60mm x 07mm x 7°, Non-Sterile	1
GA186008B	LLIF Spacer, HA PEEK, 18mm x 60mm x 08mm x 7°, Non-Sterile	2
GA186010B	LLIF Spacer, HA PEEK, 18mm x 60mm x 10mm x 7°, Non-Sterile	2
GA186012B	LLIF Spacer, HA PEEK, 18mm x 60mm x 12mm x 7°, Non-Sterile	2
GA186014B	LLIF Spacer, HA PEEK, 18mm x 60mm x 14mm x 7°, Non-Sterile	2
GA186016B	LLIF Spacer, HA PEEK, 18mm x 60mm x 16mm x 7°, Non-Sterile	1

GA184507C	LLIF Spacer, HA PEEK, 18mm x 45mm x 07mm x 12°, Non-Sterile	1
GA184508D	LLIF Spacer, HA PEEK, 18mm x 45mm x 08mm x 15°, Non-Sterile	2
GA184510D	LLIF Spacer, HA PEEK, 18mm x 45mm x 10mm x 15°, Non-Sterile	2
GA184512D	LLIF Spacer, HA PEEK, 18mm x 45mm x 12mm x 15°, Non-Sterile	2
GA184514D	LLIF Spacer, HA PEEK, 18mm x 45mm x 14mm x 15°, Non-Sterile	2
GA184516D	LLIF Spacer, HA PEEK, 18mm x 45mm x 16mm x 15°, Non-Sterile	1
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GA185012D	LLIF Spacer, HA PEEK, 18mm x 50mm x 12mm x 15°, Non-Sterile	2
GA185014D	LLIF Spacer, HA PEEK, 18mm x 50mm x 14mm x 15°, Non-Sterile	2
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GA185512D	LLIF Spacer, HA PEEK, 18mm x 55mm x 12mm x 15°, Non-Sterile	2
GA185514D	LLIF Spacer, HA PEEK, 18mm x 55mm x 14mm x 15°, Non-Sterile	2
GA185516D	LLIF Spacer, HA PEEK, 18mm x 55mm x 16mm x 15°, Non-Sterile	1
GA186007C	LLIF Spacer, HA PEEK, 18mm x 60mm x 07mm x 12°, Non-Sterile	1
GA186008D	LLIF Spacer, HA PEEK, 18mm x 60mm x 08mm x 15°, Non-Sterile	2
GA186010D	LLIF Spacer, HA PEEK, 18mm x 60mm x 10mm x 15°, Non-Sterile	2
GA186012D	LLIF Spacer, HA PEEK, 18mm x 60mm x 12mm x 15°, Non-Sterile	2
GA186014D	LLIF Spacer, HA PEEK, 18mm x 60mm x 14mm x 15°, Non-Sterile	2
GA186016D	LLIF Spacer, HA PEEK, 18mm x 60mm x 16mm x 15°, Non-Sterile	1

SIRION LATERAL LUMBAR INTERBODY FUSION
HA PEEK OFFERING

LLIF HA PEEK SPACERS

Part Number	Description	Qty
GA224507B	LLIF Spacer, HA PEEK, 22mm x 45mm x 07mm x 7°, Non-Sterile	1
GA224508B	LLIF Spacer, HA PEEK, 22mm x 45mm x 08mm x 7°, Non-Sterile	2
GA224510B	LLIF Spacer, HA PEEK, 22mm x 45mm x 10mm x 7°, Non-Sterile	2
GA224512B	LLIF Spacer, HA PEEK, 22mm x 45mm x 12mm x 7°, Non-Sterile	2
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GA225008B	LLIF Spacer, HA PEEK, 22mm x 50mm x 08mm x 7°, Non-Sterile	2
GA225010B	LLIF Spacer, HA PEEK, 22mm x 50mm x 10mm x 7°, Non-Sterile	2
GA225012B	LLIF Spacer, HA PEEK, 22mm x 50mm x 12mm x 7°, Non-Sterile	2
GA225014B	LLIF Spacer, HA PEEK, 22mm x 50mm x 14mm x 7°, Non-Sterile	2
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GA226016B	LLIF Spacer, HA PEEK, 22mm x 60mm x 16mm x 7°, Non-Sterile	1

Part Number	Description	Qty
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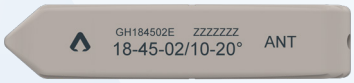
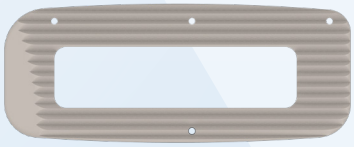
GA224510D	LLIF Spacer, HA PEEK, 22mm x 50mm x 10mm x 15°, Non-Sterile	2
GA224512D	LLIF Spacer, HA PEEK, 22mm x 50mm x 12mm x 15°, Non-Sterile	2
GA224514D	LLIF Spacer, HA PEEK, 22mm x 50mm x 14mm x 15°, Non-Sterile	2
GA224516D	LLIF Spacer, HA PEEK, 22mm x 50mm x 16mm x 15°, Non-Sterile	1
GA225507C	LLIF Spacer, HA PEEK, 22mm x 55mm x 07mm x 12°, Non-Sterile	1
GA225508D	LLIF Spacer, HA PEEK, 22mm x 55mm x 08mm x 15°, Non-Sterile	2
GA225510D	LLIF Spacer, HA PEEK, 22mm x 55mm x 10mm x 15°, Non-Sterile	2
GA225512D	LLIF Spacer, HA PEEK, 22mm x 55mm x 12mm x 15°, Non-Sterile	2
GA225514D	LLIF Spacer, HA PEEK, 22mm x 55mm x 14mm x 15°, Non-Sterile	2
GA225516D	LLIF Spacer, HA PEEK, 22mm x 55mm x 16mm x 15°, Non-Sterile	1
GA226007C	LLIF Spacer, HA PEEK, 22mm x 60mm x 07mm x 12°, Non-Sterile	1
GA226008D	LLIF Spacer, HA PEEK, 22mm x 60mm x 08mm x 15°, Non-Sterile	2
GA226010D	LLIF Spacer, HA PEEK, 22mm x 60mm x 10mm x 15°, Non-Sterile	2
GA226012D	LLIF Spacer, HA PEEK, 22mm x 60mm x 12mm x 15°, Non-Sterile	2
GA226014D	LLIF Spacer, HA PEEK, 22mm x 60mm x 14mm x 15°, Non-Sterile	2
GA226016D	LLIF Spacer, HA PEEK, 22mm x 60mm x 16mm x 15°, Non-Sterile	1

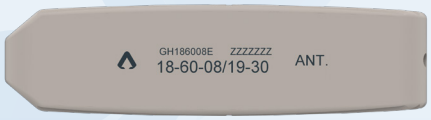
SIRION LATERAL LUMBAR INTERBODY FUSION
HA PEEK OFFERING

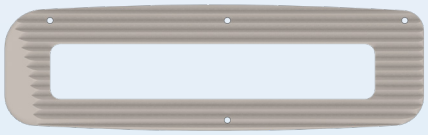
LLIF HA PEEK SPACERS

GH184502E	LLIF Spacer, HA PEEK, 18MM x 45MM x 02MM x 20°, Non-Sterile	1/OPT
GH184504E	LLIF Spacer, HA PEEK, 18MM x 45MM x 04MM x 20°, Non-Sterile	1/OPT
GH184506E	LLIF Spacer, HA PEEK, 18MM x 45MM x 06MM x 20°, Non-Sterile	1/OPT
GH184508E	LLIF Spacer, HA PEEK, 18MM x 45MM x 08MM x 20°, Non-Sterile	1/OPT
GH184510E	LLIF Spacer, HA PEEK, 18MM x 45MM x 10MM x 20°, Non-Sterile	1/OPT
GH185002E	LLIF Spacer, HA PEEK, 18MM x 50MM x 02MM x 20°, Non-Sterile	1/OPT
GH185004E	LLIF Spacer, HA PEEK, 18MM x 50MM x 04MM x 20°, Non-Sterile	1/OPT
GH185006E	LLIF Spacer, HA PEEK, 18MM x 50MM x 06MM x 20°, Non-Sterile	1/OPT
GH185008E	LLIF Spacer, HA PEEK, 18MM x 50MM x 08MM x 20°, Non-Sterile	1/OPT
GH185010E	LLIF Spacer, HA PEEK, 18MM x 50MM x 10MM x 20°, Non-Sterile	1/OPT
GH185502E	LLIF Spacer, HA PEEK, 18MM x 55MM x 02MM x 20°, Non-Sterile	1/OPT
GH185504E	LLIF Spacer, HA PEEK, 18MM x 55MM x 04MM x 20°, Non-Sterile	1/OPT
GH185506E	LLIF Spacer, HA PEEK, 18MM x 55MM x 06MM x 20°, Non-Sterile	1/OPT
GH185508E	LLIF Spacer, HA PEEK, 18MM x 55MM x 08MM x 20°, Non-Sterile	1/OPT
GH185510E	LLIF Spacer, HA PEEK, 18MM x 55MM x 10MM x 20°, Non-Sterile	1/OPT
GH186002E	LLIF Spacer, HA PEEK, 18MM x 60MM x 02MM x 20°, Non-Sterile	1/OPT
GH186004E	LLIF Spacer, HA PEEK, 18MM x 60MM x 04MM x 20°, Non-Sterile	1/OPT
GH186006E	LLIF Spacer, HA PEEK, 18MM x 60MM x 06MM x 20°, Non-Sterile	1/OPT
GH186008E	LLIF Spacer, HA PEEK, 18MM x 60MM x 08MM x 20°, Non-Sterile	1/OPT
GH186010E	LLIF Spacer, HA PEEK, 18MM x 60MM x 10MM x 20°, Non-Sterile	1/OPT
GH184502F	LLIF Spacer, HA PEEK, 18MM x 45MM x 02MM x 25°, Non-Sterile	1/OPT
GH184504F	LLIF Spacer, HA PEEK, 18MM x 45MM x 04MM x 25°, Non-Sterile	1/OPT
GH184506F	LLIF Spacer, HA PEEK, 18MM x 45MM x 06MM x 25°, Non-Sterile	1/OPT
GH184508F	LLIF Spacer, HA PEEK, 18MM x 45MM x 08MM x 25°, Non-Sterile	1/OPT
GH184510F	LLIF Spacer, HA PEEK, 18MM x 45MM x 10MM x 25°, Non-Sterile	1/OPT
GH185002F	LLIF Spacer, HA PEEK, 18MM x 50MM x 02MM x 25°, Non-Sterile	1/OPT
GH185004F	LLIF Spacer, HA PEEK, 18MM x 50MM x 04MM x 25°, Non-Sterile	1/OPT
GH185006F	LLIF Spacer, HA PEEK, 18MM x 50MM x 06MM x 25°, Non-Sterile	1/OPT
GH185008F	LLIF Spacer, HA PEEK, 18MM x 50MM x 08MM x 25°, Non-Sterile	1/OPT
GH185010F	LLIF Spacer, HA PEEK, 18MM x 50MM x 10MM x 25°, Non-Sterile	1/OPT
GH185502F	LLIF Spacer, HA PEEK, 18MM x 55MM x 02MM x 25°, Non-Sterile	1/OPT
GH185504F	LLIF Spacer, HA PEEK, 18MM x 55MM x 04MM x 25°, Non-Sterile	1/OPT
GH185506F	LLIF Spacer, HA PEEK, 18MM x 55MM x 06MM x 25°, Non-Sterile	1/OPT
GH185508F	LLIF Spacer, HA PEEK, 18MM x 55MM x 08MM x 25°, Non-Sterile	1/OPT
GH185510F	LLIF Spacer, HA PEEK, 18MM x 55MM x 10MM x 25°, Non-Sterile	1/OPT
GH186002F	LLIF Spacer, HA PEEK, 18MM x 60MM x 02MM x 25°, Non-Sterile	1/OPT
GH186004F	LLIF Spacer, HA PEEK, 18MM x 60MM x 04MM x 25°, Non-Sterile	1/OPT
GH186006F	LLIF Spacer, HA PEEK, 18MM x 60MM x 06MM x 25°, Non-Sterile	1/OPT
GH186008F	LLIF Spacer, HA PEEK, 18MM x 60MM x 08MM x 25°, Non-Sterile	1/OPT
GH186010F	LLIF Spacer, HA PEEK, 18MM x 60MM x 10MM x 25°, Non-Sterile	1/OPT
GH184502G	LLIF Spacer, HA PEEK, 18MM x 45MM x 02MM x 30°, Non-Sterile	1/OPT
GH184504G	LLIF Spacer, HA PEEK, 18MM x 45MM x 04MM x 30°, Non-Sterile	1/OPT
GH184506G	LLIF Spacer, HA PEEK, 18MM x 45MM x 06MM x 30°, Non-Sterile	1/OPT
GH184508G	LLIF Spacer, HA PEEK, 18MM x 45MM x 08MM x 30°, Non-Sterile	1/OPT
GH184510G	LLIF Spacer, HA PEEK, 18MM x 45MM x 10MM x 30°, Non-Sterile	1/OPT
GH185002G	LLIF Spacer, HA PEEK, 18MM x 50MM x 02MM x 30°, Non-Sterile	1/OPT
GH185004G	LLIF Spacer, HA PEEK, 18MM x 50MM x 04MM x 30°, Non-Sterile	1/OPT
GH185006G	LLIF Spacer, HA PEEK, 18MM x 50MM x 06MM x 30°, Non-Sterile	1/OPT
GH185008G	LLIF Spacer, HA PEEK, 18MM x 50MM x 08MM x 30°, Non-Sterile	1/OPT
GH185010G	LLIF Spacer, HA PEEK, 18MM x 50MM x 10MM x 30°, Non-Sterile	1/OPT
GH185502G	LLIF Spacer, HA PEEK, 18MM x 55MM x 02MM x 30°, Non-Sterile	1/OPT
GH185504G	LLIF Spacer, HA PEEK, 18MM x 55MM x 04MM x 30°, Non-Sterile	1/OPT
GH185506G	LLIF Spacer, HA PEEK, 18MM x 55MM x 06MM x 30°, Non-Sterile	1/OPT
GH185508G	LLIF Spacer, HA PEEK, 18MM x 55MM x 08MM x 30°, Non-Sterile	1/OPT
GH185510G	LLIF Spacer, HA PEEK, 18MM x 55MM x 10MM x 30°, Non-Sterile	1/OPT
GH186002G	LLIF Spacer, HA PEEK, 18MM x 60MM x 02MM x 30°, Non-Sterile	1/OPT
GH186004G	LLIF Spacer, HA PEEK, 18MM x 60MM x 04MM x 30°, Non-Sterile	1/OPT
GH186006G	LLIF Spacer, HA PEEK, 18MM x 60MM x 06MM x 30°, Non-Sterile	1/OPT
GH186008G	LLIF Spacer, HA PEEK, 18MM x 60MM x 08MM x 30°, Non-Sterile	1/OPT
GH186010G	LLIF Spacer, HA PEEK, 18MM x 60MM x 10MM x 30°, Non-Sterile	1/OPT









SIRION LATERAL LUMBAR INTERBODY FUSION HA PEEK OFFERING

LLIF HA PEEK SPACERS

	Description	Qty
GH224502E	LLIF Spacer, HA PEEK, 22MM x 45MM x 02MM x 20°, Non-Sterile	1/OPT
GH224504E	LLIF Spacer, HA PEEK, 22MM x 45MM x 04MM x 20°, Non-Sterile	1/OPT
GH224506E	LLIF Spacer, HA PEEK, 22MM x 45MM x 06MM x 20°, Non-Sterile	1/OPT
GH224508E	LLIF Spacer, HA PEEK, 22MM x 45MM x 08MM x 20°, Non-Sterile	1/OPT
GH224510E	LLIF Spacer, HA PEEK, 22MM x 45MM x 10MM x 20°, Non-Sterile	1/OPT
GH225002E	LLIF Spacer, HA PEEK, 22MM x 50MM x 02MM x 20°, Non-Sterile	1/OPT
GH225004E	LLIF Spacer, HA PEEK, 22MM x 50MM x 04MM x 20°, Non-Sterile	1/OPT
GH225006E	LLIF Spacer, HA PEEK, 22MM x 50MM x 06MM x 20°, Non-Sterile	1/OPT
GH225008E	LLIF Spacer, HA PEEK, 22MM x 50MM x 08MM x 20°, Non-Sterile	1/OPT
GH225010E	LLIF Spacer, HA PEEK, 22MM x 50MM x 10MM x 20°, Non-Sterile	1/OPT
GH225502E	LLIF Spacer, HA PEEK, 22MM x 55MM x 02MM x 20°, Non-Sterile	1/OPT
GH225504E	LLIF Spacer, HA PEEK, 22MM x 55MM x 04MM x 20°, Non-Sterile	1/OPT
GH225506E	LLIF Spacer, HA PEEK, 22MM x 55MM x 06MM x 20°, Non-Sterile	1/OPT
GH225508E	LLIF Spacer, HA PEEK, 22MM x 55MM x 08MM x 20°, Non-Sterile	1/OPT
GH225510E	LLIF Spacer, HA PEEK, 22MM x 55MM x 10MM x 20°, Non-Sterile	1/OPT
GH226002E	LLIF Spacer, HA PEEK, 22MM x 60MM x 02MM x 20°, Non-Sterile	1/OPT
GH226004E	LLIF Spacer, HA PEEK, 22MM x 60MM x 04MM x 20°, Non-Sterile	1/OPT
GH226006E	LLIF Spacer, HA PEEK, 22MM x 60MM x 06MM x 20°, Non-Sterile	1/OPT
GH226008E	LLIF Spacer, HA PEEK, 22MM x 60MM x 08MM x 20°, Non-Sterile	1/OPT
GH226010E	LLIF Spacer, HA PEEK, 22MM x 60MM x 10MM x 20°, Non-Sterile	1/OPT
GH224502F	LLIF Spacer, HA PEEK, 22MM x 45MM x 02MM x 25°, Non-Sterile	1/OPT
GH224504F	LLIF Spacer, HA PEEK, 22MM x 45MM x 04MM x 25°, Non-Sterile	1/OPT
GH224506F	LLIF Spacer, HA PEEK, 22MM x 45MM x 06MM x 25°, Non-Sterile	1/OPT
GH224508F	LLIF Spacer, HA PEEK, 22MM x 45MM x 08MM x 25°, Non-Sterile	1/OPT
GH224510F	LLIF Spacer, HA PEEK, 22MM x 45MM x 10MM x 25°, Non-Sterile	1/OPT
GH225002F	LLIF Spacer, HA PEEK, 22MM x 50MM x 02MM x 25°, Non-Sterile	1/OPT
GH225004F	LLIF Spacer, HA PEEK, 22MM x 50MM x 04MM x 25°, Non-Sterile	1/OPT
GH225006F	LLIF Spacer, HA PEEK, 22MM x 50MM x 06MM x 25°, Non-Sterile	1/OPT
GH225008F	LLIF Spacer, HA PEEK, 22MM x 50MM x 08MM x 25°, Non-Sterile	1/OPT
GH225010F	LLIF Spacer, HA PEEK, 22MM x 50MM x 10MM x 25°, Non-Sterile	1/OPT
GH225502F	LLIF Spacer, HA PEEK, 22MM x 55MM x 02MM x 25°, Non-Sterile	1/OPT
GH225504F	LLIF Spacer, HA PEEK, 22MM x 55MM x 04MM x 25°, Non-Sterile	1/OPT
GH225506F	LLIF Spacer, HA PEEK, 22MM x 55MM x 06MM x 25°, Non-Sterile	1/OPT
GH225508F	LLIF Spacer, HA PEEK, 22MM x 55MM x 08MM x 25°, Non-Sterile	1/OPT
GH225510F	LLIF Spacer, HA PEEK, 22MM x 55MM x 10MM x 25°, Non-Sterile	1/OPT
GH226002F	LLIF Spacer, HA PEEK, 22MM x 60MM x 02MM x 25°, Non-Sterile	1/OPT
GH226004F	LLIF Spacer, HA PEEK, 22MM x 60MM x 04MM x 25°, Non-Sterile	1/OPT
GH226006F	LLIF Spacer, HA PEEK, 22MM x 60MM x 06MM x 25°, Non-Sterile	1/OPT
GH226008F	LLIF Spacer, HA PEEK, 22MM x 60MM x 08MM x 25°, Non-Sterile	1/OPT
GH226010F	LLIF Spacer, HA PEEK, 22MM x 60MM x 10MM x 25°, Non-Sterile	1/OPT
GH224502G	LLIF Spacer, HA PEEK, 22MM x 45MM x 02MM x 30°, Non-Sterile	1/OPT
GH224504G	LLIF Spacer, HA PEEK, 22MM x 45MM x 04MM x 30°, Non-Sterile	1/OPT
GH224506G	LLIF Spacer, HA PEEK, 22MM x 45MM x 06MM x 30°, Non-Sterile	1/OPT
GH224508G	LLIF Spacer, HA PEEK, 22MM x 45MM x 08MM x 30°, Non-Sterile	1/OPT
GH224510G	LLIF Spacer, HA PEEK, 22MM x 45MM x 10MM x 30°, Non-Sterile	1/OPT
GH225002G	LLIF Spacer, HA PEEK, 22MM x 50MM x 02MM x 30°, Non-Sterile	1/OPT
GH225004G	LLIF Spacer, HA PEEK, 22MM x 50MM x 04MM x 30°, Non-Sterile	1/OPT
GH225006G	LLIF Spacer, HA PEEK, 22MM x 50MM x 06MM x 30°, Non-Sterile	1/OPT
GH225008G	LLIF Spacer, HA PEEK, 22MM x 50MM x 08MM x 30°, Non-Sterile	1/OPT
GH225010G	LLIF Spacer, HA PEEK, 22MM x 50MM x 10MM x 30°, Non-Sterile	1/OPT
GH225502G	LLIF Spacer, HA PEEK, 22MM x 55MM x 02MM x 30°, Non-Sterile	1/OPT
GH225504G	LLIF Spacer, HA PEEK, 22MM x 55MM x 04MM x 30°, Non-Sterile	1/OPT
GH225506G	LLIF Spacer, HA PEEK, 22MM x 55MM x 06MM x 30°, Non-Sterile	1/OPT
GH225508G	LLIF Spacer, HA PEEK, 22MM x 55MM x 08MM x 30°, Non-Sterile	1/OPT
GH225510G	LLIF Spacer, HA PEEK, 22MM x 55MM x 10MM x 30°, Non-Sterile	1/OPT
GH226002G	LLIF Spacer, HA PEEK, 22MM x 60MM x 02MM x 30°, Non-Sterile	1/OPT
GH226004G	LLIF Spacer, HA PEEK, 22MM x 60MM x 04MM x 30°, Non-Sterile	1/OPT
GH226006G	LLIF Spacer, HA PEEK, 22MM x 60MM x 06MM x 30°, Non-Sterile	1/OPT
GH226008G	LLIF Spacer, HA PEEK, 22MM x 60MM x 08MM x 30°, Non-Sterile	1/OPT
GH226010G	LLIF Spacer, HA PEEK, 22MM x 60MM x 10MM x 30°, Non-Sterile	1/OPT

SIRION LATERAL LUMBAR INTERBODY FUSION
ACID-ETCHED TITANIUM OFFERING

LLIF ACID-ETCHED TITANIUM SPACERS

Part Number	Description	Qty
GB184507B	LLIF Spacer, Acid-etched Titanium, 18mm x 45mm x 07mm x 7°, Non-Sterile	1
GB184508B	LLIF Spacer, Acid-etched Titanium, 18mm x 45mm x 08mm x 7°, Non-Sterile	2
GB184510B	LLIF Spacer, Acid-etched Titanium, 18mm x 45mm x 10mm x 7°, Non-Sterile	2
GB184512B	LLIF Spacer, Acid-etched Titanium, 18mm x 45mm x 12mm x 7°, Non-Sterile	2
GB184514B	LLIF Spacer, Acid-etched Titanium, 18mm x 45mm x 14mm x 7°, Non-Sterile	2
GB184516B	LLIF Spacer, Acid-etched Titanium, 18mm x 45mm x 16mm x 7°, Non-Sterile	1
GB185007B	LLIF Spacer, Acid-etched Titanium, 18mm x 50mm x 07mm x 7°, Non-Sterile	1
GB185008B	LLIF Spacer, Acid-etched Titanium, 18mm x 50mm x 08mm x 7°, Non-Sterile	2
GB185010B	LLIF Spacer, Acid-etched Titanium, 18mm x 50mm x 10mm x 7°, Non-Sterile	2
GB185012B	LLIF Spacer, Acid-etched Titanium, 18mm x 50mm x 12mm x 7°, Non-Sterile	2
GB185014B	LLIF Spacer, Acid-etched Titanium, 18mm x 50mm x 14mm x 7°, Non-Sterile	2
GB185016B	LLIF Spacer, Acid-etched Titanium, 18mm x 50mm x 16mm x 7°, Non-Sterile	1
GB185507B	LLIF Spacer, Acid-etched Titanium, 18mm x 55mm x 07mm x 7°, Non-Sterile	1
GB185508B	LLIF Spacer, Acid-etched Titanium, 18mm x 55mm x 08mm x 7°, Non-Sterile	2
GB185510B	LLIF Spacer, Acid-etched Titanium, 18mm x 55mm x 10mm x 7°, Non-Sterile	2
GB185512B	LLIF Spacer, Acid-etched Titanium, 18mm x 55mm x 12mm x 7°, Non-Sterile	2
GB185514B	LLIF Spacer, Acid-etched Titanium, 18mm x 55mm x 14mm x 7°, Non-Sterile	2
GB185516B	LLIF Spacer, Acid-etched Titanium, 18mm x 55mm x 16mm x 7°, Non-Sterile	1
GB186007B	LLIF Spacer, Acid-etched Titanium, 18mm x 60mm x 07mm x 7°, Non-Sterile	1
GB186008B	LLIF Spacer, Acid-etched Titanium, 18mm x 60mm x 08mm x 7°, Non-Sterile	2
GB186010B	LLIF Spacer, Acid-etched Titanium, 18mm x 60mm x 10mm x 7°, Non-Sterile	2
GB186012B	LLIF Spacer, Acid-etched Titanium, 18mm x 60mm x 12mm x 7°, Non-Sterile	2
GB186014B	LLIF Spacer, Acid-etched Titanium, 18mm x 60mm x 14mm x 7°, Non-Sterile	2
GB186016B	LLIF Spacer, Acid-etched Titanium, 18mm x 60mm x 16mm x 7°, Non-Sterile	1

GB184507C	LLIF Spacer, Acid-etched Titanium, 18mm x 45mm x 07mm x 12°, Non-Sterile	1
GB184508D	LLIF Spacer, Acid-etched Titanium, 18mm x 45mm x 08mm x 15°, Non-Sterile	2
GB184510D	LLIF Spacer, Acid-etched Titanium, 18mm x 45mm x 10mm x 15°, Non-Sterile	2
GB184512D	LLIF Spacer, Acid-etched Titanium, 18mm x 45mm x 12mm x 15°, Non-Sterile	2
GB184514D	LLIF Spacer, Acid-etched Titanium, 18mm x 45mm x 14mm x 15°, Non-Sterile	2
GB184516D	LLIF Spacer, Acid-etched Titanium, 18mm x 45mm x 16mm x 15°, Non-Sterile	1
GB185007C	LLIF Spacer, Acid-etched Titanium, 18mm x 50mm x 07mm x 12°, Non-Sterile	1
GB185008D	LLIF Spacer, Acid-etched Titanium, 18mm x 50mm x 08mm x 15°, Non-Sterile	2
GB185010D	LLIF Spacer, Acid-etched Titanium, 18mm x 50mm x 10mm x 15°, Non-Sterile	2
GB185012D	LLIF Spacer, Acid-etched Titanium, 18mm x 50mm x 12mm x 15°, Non-Sterile	2
GB185014D	LLIF Spacer, Acid-etched Titanium, 18mm x 50mm x 14mm x 15°, Non-Sterile	2
GB185016D	LLIF Spacer, Acid-etched Titanium, 18mm x 50mm x 16mm x 15°, Non-Sterile	1
GB185507C	LLIF Spacer, Acid-etched Titanium, 18mm x 55mm x 07mm x 12°, Non-Sterile	1
GB185508D	LLIF Spacer, Acid-etched Titanium, 18mm x 55mm x 08mm x 15°, Non-Sterile	2
GB185510D	LLIF Spacer, Acid-etched Titanium, 18mm x 55mm x 10mm x 15°, Non-Sterile	2
GB185512D	LLIF Spacer, Acid-etched Titanium, 18mm x 55mm x 12mm x 15°, Non-Sterile	2
GB185514D	LLIF Spacer, Acid-etched Titanium, 18mm x 55mm x 14mm x 15°, Non-Sterile	2
GB185516D	LLIF Spacer, Acid-etched Titanium, 18mm x 55mm x 16mm x 15°, Non-Sterile	1
GB186007C	LLIF Spacer, Acid-etched Titanium, 18mm x 60mm x 07mm x 12°, Non-Sterile	1
GB186008D	LLIF Spacer, Acid-etched Titanium, 18mm x 60mm x 08mm x 15°, Non-Sterile	2
GB186010D	LLIF Spacer, Acid-etched Titanium, 18mm x 60mm x 10mm x 15°, Non-Sterile	2
GB186012D	LLIF Spacer, Acid-etched Titanium, 18mm x 60mm x 12mm x 15°, Non-Sterile	2
GB186014D	LLIF Spacer, Acid-etched Titanium, 18mm x 60mm x 14mm x 15°, Non-Sterile	2
GB186016D	LLIF Spacer, Acid-etched Titanium, 18mm x 60mm x 16mm x 15°, Non-Sterile	1
GB224507B	LLIF Spacer, Acid-etched Titanium, 22mm x 45mm x 07mm x 7°, Non-Sterile	1
GB224508B	LLIF Spacer, Acid-etched Titanium, 22mm x 45mm x 08mm x 7°, Non-Sterile	2
GB224510B	LLIF Spacer, Acid-etched Titanium, 22mm x 45mm x 10mm x 7°, Non-Sterile	2
GB224512B	LLIF Spacer, Acid-etched Titanium, 22mm x 45mm x 12mm x 7°, Non-Sterile	2
GB224514B	LLIF Spacer, Acid-etched Titanium, 22mm x 45mm x 14mm x 7°, Non-Sterile	2
GB224516B	LLIF Spacer, Acid-etched Titanium, 22mm x 45mm x 16mm x 7°, Non-Sterile	1

SIRION LATERAL LUMBAR INTERBODY FUSION
ACID-ETCHED TITANIUM OFFERING

LLIF ACID-ETCHED TITANIUM SPACERS

Part Number	Description	Qty
GB225007B	LLIF Spacer, Acid-etched Titanium, 22mm x 50mm x 07mm x 7°, Non-Sterile	1
GB225008B	LLIF Spacer, Acid-etched Titanium, 22mm x 50mm x 08mm x 7°, Non-Sterile	2
GB225010B	LLIF Spacer, Acid-etched Titanium, 22mm x 50mm x 10mm x 7°, Non-Sterile	2
GB225012B	LLIF Spacer, Acid-etched Titanium, 22mm x 50mm x 12mm x 7°, Non-Sterile	2
GB225014B	LLIF Spacer, Acid-etched Titanium, 22mm x 50mm x 14mm x 7°, Non-Sterile	2
GB225016B	LLIF Spacer, Acid-etched Titanium, 22mm x 50mm x 16mm x 7°, Non-Sterile	1
GB225507B	LLIF Spacer, Acid-etched Titanium, 22mm x 55mm x 07mm x 7°, Non-Sterile	1
GB225508B	LLIF Spacer, Acid-etched Titanium, 22mm x 55mm x 08mm x 7°, Non-Sterile	2
GB225510B	LLIF Spacer, Acid-etched Titanium, 22mm x 55mm x 10mm x 7°, Non-Sterile	2
GB225512B	LLIF Spacer, Acid-etched Titanium, 22mm x 55mm x 12mm x 7°, Non-Sterile	2
GB225514B	LLIF Spacer, Acid-etched Titanium, 22mm x 55mm x 14mm x 7°, Non-Sterile	2
GB225516B	LLIF Spacer, Acid-etched Titanium, 22mm x 55mm x 16mm x 7°, Non-Sterile	1
GB226007B	LLIF Spacer, Acid-etched Titanium, 22mm x 60mm x 07mm x 7°, Non-Sterile	1
GB226008B	LLIF Spacer, Acid-etched Titanium, 22mm x 60mm x 08mm x 7°, Non-Sterile	2
GB226010B	LLIF Spacer, Acid-etched Titanium, 22mm x 60mm x 10mm x 7°, Non-Sterile	2
GB226012B	LLIF Spacer, Acid-etched Titanium, 22mm x 60mm x 12mm x 7°, Non-Sterile	2
GB226014B	LLIF Spacer, Acid-etched Titanium, 22mm x 60mm x 14mm x 7°, Non-Sterile	2
GB226016B	LLIF Spacer, Acid-etched Titanium, 22mm x 60mm x 16mm x 7°, Non-Sterile	1

GB224507C	LLIF Spacer, Acid-etched Titanium, 22mm x 45mm x 07mm x 12°, Non-Sterile	1
GB224508D	LLIF Spacer, Acid-etched Titanium, 22mm x 45mm x 08mm x 15°, Non-Sterile	2
GB224510D	LLIF Spacer, Acid-etched Titanium, 22mm x 45mm x 10mm x 15°, Non-Sterile	2
GB224512D	LLIF Spacer, Acid-etched Titanium, 22mm x 45mm x 12mm x 15°, Non-Sterile	2
GB224514D	LLIF Spacer, Acid-etched Titanium, 22mm x 45mm x 14mm x 15°, Non-Sterile	2
GB224516D	LLIF Spacer, Acid-etched Titanium, 22mm x 45mm x 16mm x 15°, Non-Sterile	1
GB225007C	LLIF Spacer, Acid-etched Titanium, 22mm x 50mm x 07mm x 12°, Non-Sterile	1
GB225008D	LLIF Spacer, Acid-etched Titanium, 22mm x 50mm x 08mm x 15°, Non-Sterile	2
GB225010D	LLIF Spacer, Acid-etched Titanium, 22mm x 50mm x 10mm x 15°, Non-Sterile	2
GB225012D	LLIF Spacer, Acid-etched Titanium, 22mm x 50mm x 12mm x 15°, Non-Sterile	2
GB225014D	LLIF Spacer, Acid-etched Titanium, 22mm x 50mm x 14mm x 15°, Non-Sterile	2
GB225016D	LLIF Spacer, Acid-etched Titanium, 22mm x 50mm x 16mm x 15°, Non-Sterile	1
GB225507C	LLIF Spacer, Acid-etched Titanium, 22mm x 55mm x 07mm x 12°, Non-Sterile	1
GB225508D	LLIF Spacer, Acid-etched Titanium, 22mm x 55mm x 08mm x 15°, Non-Sterile	2
GB225510D	LLIF Spacer, Acid-etched Titanium, 22mm x 55mm x 10mm x 15°, Non-Sterile	2
GB225512D	LLIF Spacer, Acid-etched Titanium, 22mm x 55mm x 12mm x 15°, Non-Sterile	2
GB225514D	LLIF Spacer, Acid-etched Titanium, 22mm x 55mm x 14mm x 15°, Non-Sterile	2
GB225516D	LLIF Spacer, Acid-etched Titanium, 22mm x 55mm x 16mm x 15°, Non-Sterile	1
GB226007C	LLIF Spacer, Acid-etched Titanium, 22mm x 60mm x 07mm x 12°, Non-Sterile	1
GB226008D	LLIF Spacer, Acid-etched Titanium, 22mm x 60mm x 08mm x 15°, Non-Sterile	2
GB226010D	LLIF Spacer, Acid-etched Titanium, 22mm x 60mm x 10mm x 15°, Non-Sterile	2
GB226012D	LLIF Spacer, Acid-etched Titanium, 22mm x 60mm x 12mm x 15°, Non-Sterile	2
GB226014D	LLIF Spacer, Acid-etched Titanium, 22mm x 60mm x 14mm x 15°, Non-Sterile	2
GB226016D	LLIF Spacer, Acid-etched Titanium, 22mm x 60mm x 16mm x 15°, Non-Sterile	1

SIRION LATERAL LUMBAR INTERBODY FUSION
ACID-ETCHED TITANIUM OFFERING

LLIF ACID-ETCHED TITANIUM SPACERS

GJ184502E	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 02MM x 20°, Non-Sterile	1/OPT
GJ184504E	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 04MM x 20°, Non-Sterile	1/OPT
GJ184506E	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 06MM x 20°, Non-Sterile	1/OPT
GJ184508E	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 08MM x 20°, Non-Sterile	1/OPT
GJ184510E	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 10MM x 20°, Non-Sterile	1/OPT
GJ185002E	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 02MM x 20°, Non-Sterile	1/OPT
GJ185004E	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 04MM x 20°, Non-Sterile	1/OPT
GJ185006E	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 06MM x 20°, Non-Sterile	1/OPT
GJ185008E	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 08MM x 20°, Non-Sterile	1/OPT
GJ185010E	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 10MM x 20°, Non-Sterile	1/OPT
GJ185502E	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 02MM x 20°, Non-Sterile	1/OPT
GJ185504E	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 04MM x 20°, Non-Sterile	1/OPT
GJ185506E	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 06MM x 20°, Non-Sterile	1/OPT
GJ185508E	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 08MM x 20°, Non-Sterile	1/OPT
GJ185510E	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 10MM x 20°, Non-Sterile	1/OPT
GJ186002E	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 02MM x 20°, Non-Sterile	1/OPT
GJ186004E	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 04MM x 20°, Non-Sterile	1/OPT
GJ186006E	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 06MM x 20°, Non-Sterile	1/OPT
GJ186008E	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 08MM x 20°, Non-Sterile	1/OPT
GJ186010E	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 10MM x 20°, Non-Sterile	1/OPT
GJ184502F	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 02MM x 25°, Non-Sterile	1/OPT
GJ184504F	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 04MM x 25°, Non-Sterile	1/OPT
GJ184506F	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 06MM x 25°, Non-Sterile	1/OPT
GJ184508F	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 08MM x 25°, Non-Sterile	1/OPT
GJ184510F	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 10MM x 25°, Non-Sterile	1/OPT
GJ185002F	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 02MM x 25°, Non-Sterile	1/OPT
GJ185004F	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 04MM x 25°, Non-Sterile	1/OPT
GJ185006F	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 06MM x 25°, Non-Sterile	1/OPT
GJ185008F	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 08MM x 25°, Non-Sterile	1/OPT
GJ185010F	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 10MM x 25°, Non-Sterile	1/OPT
GJ185502F	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 02MM x 25°, Non-Sterile	1/OPT
GJ185504F	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 04MM x 25°, Non-Sterile	1/OPT
GJ185506F	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 06MM x 25°, Non-Sterile	1/OPT
GJ185508F	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 08MM x 25°, Non-Sterile	1/OPT
GJ185510F	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 10MM x 25°, Non-Sterile	1/OPT
GJ186002F	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 02MM x 25°, Non-Sterile	1/OPT
GJ186004F	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 04MM x 25°, Non-Sterile	1/OPT
GJ186006F	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 06MM x 25°, Non-Sterile	1/OPT
GJ186008F	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 08MM x 25°, Non-Sterile	1/OPT
GJ186010F	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 10MM x 25°, Non-Sterile	1/OPT
GJ184502G	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 02MM x 30°, Non-Sterile	1/OPT
GJ184504G	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 04MM x 30°, Non-Sterile	1/OPT
GJ184506G	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 06MM x 30°, Non-Sterile	1/OPT
GJ184508G	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 08MM x 30°, Non-Sterile	1/OPT
GJ184510G	LLIF Spacer, Acid-etched Titanium, 18MM x 45MM x 10MM x 30°, Non-Sterile	1/OPT
GJ185002G	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 02MM x 30°, Non-Sterile	1/OPT
GJ185004G	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 04MM x 30°, Non-Sterile	1/OPT
GJ185006G	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 06MM x 30°, Non-Sterile	1/OPT
GJ185008G	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 08MM x 30°, Non-Sterile	1/OPT
GJ185010G	LLIF Spacer, Acid-etched Titanium, 18MM x 50MM x 10MM x 30°, Non-Sterile	1/OPT
GJ185502G	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 02MM x 30°, Non-Sterile	1/OPT
GJ185504G	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 04MM x 30°, Non-Sterile	1/OPT
GJ185506G	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 06MM x 30°, Non-Sterile	1/OPT
GJ185508G	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 08MM x 30°, Non-Sterile	1/OPT
GJ185510G	LLIF Spacer, Acid-etched Titanium, 18MM x 55MM x 10MM x 30°, Non-Sterile	1/OPT
GJ186002G	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 02MM x 30°, Non-Sterile	1/OPT
GJ186004G	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 04MM x 30°, Non-Sterile	1/OPT
GJ186006G	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 06MM x 30°, Non-Sterile	1/OPT
GJ186008G	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 08MM x 30°, Non-Sterile	1/OPT
GJ186010G	LLIF Spacer, Acid-etched Titanium, 18MM x 60MM x 10MM x 30°, Non-Sterile	1/OPT

LLIF ACID-ETCHED TITANIUM SPACERS

Part Number	Description	Qty
GJ224502E	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 02MM x 20°, Non-Sterile	1/OPT
GJ224504E	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 04MM x 20°, Non-Sterile	1/OPT
GJ224506E	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 06MM x 20°, Non-Sterile	1/OPT
GJ224508E	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 08MM x 20°, Non-Sterile	1/OPT
GJ224510E	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 10MM x 20°, Non-Sterile	1/OPT
GJ225002E	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 02MM x 20°, Non-Sterile	1/OPT
GJ225004E	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 04MM x 20°, Non-Sterile	1/OPT
GJ225006E	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 06MM x 20°, Non-Sterile	1/OPT
GJ225008E	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 08MM x 20°, Non-Sterile	1/OPT
GJ225010E	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 10MM x 20°, Non-Sterile	1/OPT
GJ225502E	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 02MM x 20°, Non-Sterile	1/OPT
GJ225504E	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 04MM x 20°, Non-Sterile	1/OPT
GJ225506E	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 06MM x 20°, Non-Sterile	1/OPT
GJ225508E	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 08MM x 20°, Non-Sterile	1/OPT
GJ225510E	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 10MM x 20°, Non-Sterile	1/OPT
GJ226002E	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 02MM x 20°, Non-Sterile	1/OPT
GJ226004E	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 04MM x 20°, Non-Sterile	1/OPT
GJ226006E	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 06MM x 20°, Non-Sterile	1/OPT
GJ226008E	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 08MM x 20°, Non-Sterile	1/OPT
GJ226010E	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 10MM x 20°, Non-Sterile	1/OPT
GJ224502F	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 02MM x 25°, Non-Sterile	1/OPT
GJ224504F	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 04MM x 25°, Non-Sterile	1/OPT
GJ224506F	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 06MM x 25°, Non-Sterile	1/OPT
GJ224508F	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 08MM x 25°, Non-Sterile	1/OPT
GJ224510F	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 10MM x 25°, Non-Sterile	1/OPT
GJ225002F	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 02MM x 25°, Non-Sterile	1/OPT
GJ225004F	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 04MM x 25°, Non-Sterile	1/OPT
GJ225006F	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 06MM x 25°, Non-Sterile	1/OPT
GJ225008F	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 08MM x 25°, Non-Sterile	1/OPT
GJ225010F	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 10MM x 25°, Non-Sterile	1/OPT
GJ225502F	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 02MM x 25°, Non-Sterile	1/OPT
GJ225504F	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 04MM x 25°, Non-Sterile	1/OPT
GJ225506F	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 06MM x 25°, Non-Sterile	1/OPT
GJ225508F	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 08MM x 25°, Non-Sterile	1/OPT
GJ225510F	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 10MM x 25°, Non-Sterile	1/OPT
GJ226002F	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 02MM x 25°, Non-Sterile	1/OPT
GJ226004F	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 04MM x 25°, Non-Sterile	1/OPT
GJ226006F	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 06MM x 25°, Non-Sterile	1/OPT
GJ226008F	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 08MM x 25°, Non-Sterile	1/OPT
GJ226010F	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 10MM x 25°, Non-Sterile	1/OPT
GJ224502G	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 02MM x 30°, Non-Sterile	1/OPT
GJ224504G	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 04MM x 30°, Non-Sterile	1/OPT
GJ224506G	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 06MM x 30°, Non-Sterile	1/OPT
GJ224508G	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 08MM x 30°, Non-Sterile	1/OPT
GJ224510G	LLIF Spacer, Acid-etched Titanium, 22MM x 45MM x 10MM x 30°, Non-Sterile	1/OPT
GJ225002G	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 02MM x 30°, Non-Sterile	1/OPT
GJ225004G	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 04MM x 30°, Non-Sterile	1/OPT
GJ225006G	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 06MM x 30°, Non-Sterile	1/OPT
GJ225008G	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 08MM x 30°, Non-Sterile	1/OPT
GJ225010G	LLIF Spacer, Acid-etched Titanium, 22MM x 50MM x 10MM x 30°, Non-Sterile	1/OPT
GJ225502G	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 02MM x 30°, Non-Sterile	1/OPT
GJ225504G	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 04MM x 30°, Non-Sterile	1/OPT
GJ225506G	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 06MM x 30°, Non-Sterile	1/OPT
GJ225508G	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 08MM x 30°, Non-Sterile	1/OPT
GJ225510G	LLIF Spacer, Acid-etched Titanium, 22MM x 55MM x 10MM x 30°, Non-Sterile	1/OPT
GJ226002G	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 02MM x 30°, Non-Sterile	1/OPT
GJ226004G	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 04MM x 30°, Non-Sterile	1/OPT
GJ226006G	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 06MM x 30°, Non-Sterile	1/OPT
GJ226008G	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 08MM x 30°, Non-Sterile	1/OPT
GJ226010G	LLIF Spacer, Acid-etched Titanium, 22MM x 60MM x 10MM x 30°, Non-Sterile	1/OPT

SIRION LATERAL LUMBAR INTERBODY FUSION PLATE OFFERING

LATERAL PLATE, ATTACHED, 1 HOLE

Part Number	Description	Qty
GCDAAZZ08	Lateral Plate, Attached, 1 Hole, 8mm	2
GCDAAZZ10	Lateral Plate, Attached, 1 Hole, 10mm	2
GCDAAZZ12	Lateral Plate, Attached, 1 Hole, 12mm	2
GCDAAZZ14	Lateral Plate, Attached, 1 Hole, 14mm	2
GCDAAZZ16	Lateral Plate, Attached, 1 Hole, 16mm	2
GCDAAZZ18	Lateral Plate, Attached, 1 Hole, 18mm	2 / Opt.
GCDAAZZ20	Lateral Plate, Attached, 1 Hole, 20mm	2 / Opt.

LATERAL PLATE, ATTACHED, 2 HOLE

Part Number	Description	Qty
GCDBAZZ08	Lateral Plate, Attached, 2 Hole, 8mm	2
GCDBAZZ10	Lateral Plate, Attached, 2 Hole, 10mm	2
GCDBAZZ12	Lateral Plate, Attached, 2 Hole, 12mm	2
GCDBAZZ14	Lateral Plate, Attached, 2 Hole, 14mm	2
GCDBAZZ16	Lateral Plate, Attached, 2 Hole, 16mm	2
GCDBAZZ18	Lateral Plate, Attached, 2 Hole, 18mm	2 / Opt.
GCDBAZZ20	Lateral Plate, Attached, 2 Hole, 20mm	2 / Opt.

LATERAL PLATE, ATTACHED, 4 HOLE

Part Number	Description	Qty
GCDCAZZ08	Lateral Plate, Attached, 4 Hole, 8mm	2
GCDCAZZ10	Lateral Plate, Attached, 4 Hole, 10mm	2
GCDCAZZ12	Lateral Plate, Attached, 4 Hole, 12mm	2
GCDCAZZ14	Lateral Plate, Attached, 4 Hole, 14mm	2
GCDCAZZ16	Lateral Plate, Attached, 4 Hole, 16mm	2
GCDCAZZ18	Lateral Plate, Attached, 4 Hole, 18mm	2 / Opt.
GCDCAZZ20	Lateral Plate, Attached, 4 Hole, 20mm	2 / Opt.

LATERAL PLATE, DETACHED, 1 HOLE

Part Number	Description	Qty
GCDABZZ07	Lateral Plate, Detached, 1 Hole, 7mm	2
GCDABZZ08	Lateral Plate, Detached, 1 Hole, 8mm	2
GCDABZZ10	Lateral Plate, Detached, 1 Hole, 10mm	2
GCDABZZ12	Lateral Plate, Detached, 1 Hole, 12mm	2
GCDABZZ14	Lateral Plate, Detached, 1 Hole, 14mm	2
GCDABZZ16	Lateral Plate, Detached, 1 Hole, 16mm	2
GCDABZZ18	Lateral Plate, Detached, 1 Hole, 18mm	2 / Opt.
GCDABZZ20	Lateral Plate, Detached, 1 Hole, 20mm	2 / Opt.

LATERAL PLATE, DETACHED, 2 HOLE

Part Number	Description	Qty
GCDBBZZ07	Lateral Plate, Detached, 2 Hole, 7mm	2
GCDBBZZ08	Lateral Plate, Detached, 2 Hole, 8mm	2
GCDBBZZ10	Lateral Plate, Detached, 2 Hole, 10mm	2
GCDBBZZ12	Lateral Plate, Detached, 2 Hole, 12mm	2
GCDBBZZ14	Lateral Plate, Detached, 2 Hole, 14mm	2
GCDBBZZ16	Lateral Plate, Detached, 2 Hole, 16mm	2
GCDBBZZ18	Lateral Plate, Detached, 2 Hole, 18mm	2 / Opt.
GCDBBZZ20	Lateral Plate, Detached, 2 Hole, 22mm	2 / Opt.

LATERAL PLATE, DETACHED, 4 HOLE

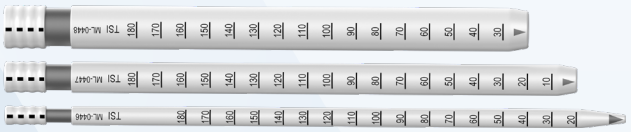
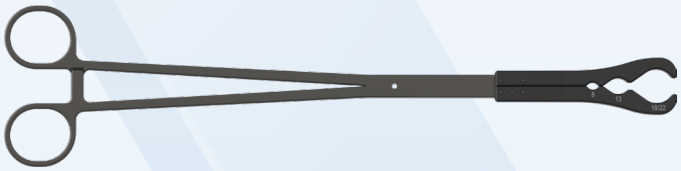
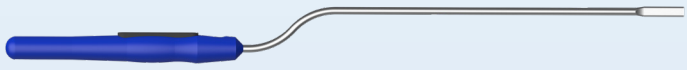
Part Number	Description	Qty
GCDCBZZ07	Lateral Plate, Detached, 4 Hole, 7mm	2
GCDCBZZ08	Lateral Plate, Detached, 4 Hole, 8mm	2
GCDCBZZ10	Lateral Plate, Detached, 4 Hole, 10mm	2
GCDCBZZ12	Lateral Plate, Detached, 4 Hole, 12mm	2
GCDCBZZ14	Lateral Plate, Detached, 4 Hole, 14mm	2
GCDCBZZ16	Lateral Plate, Detached, 4 Hole, 16mm	2
GCDCBZZ18	Lateral Plate, Detached, 4 Hole, 18mm	2 / Opt.
GCDCBZZ20	Lateral Plate, Detached, 4 Hole, 20mm	2 / Opt.

SIRION LATERAL LUMBAR INTERBODY FUSION PLATE SCREWS OFFERING

LATERAL PLATE SCREW SELF-DRILLING

Part Number	Description	Qty
GDDAB5530	Lateral Plate, Screw, 5.5mm x 30mm, Self Drilling, Variable Angle	8
GDDAB5535	Lateral Plate, Screw, 5.5mm x 35mm, Self Drilling, Variable Angle	8
GDDAB5540	Lateral Plate, Screw, 5.5mm x 40mm, Self Drilling, Variable Angle	8
GDDAB5545	Lateral Plate, Screw, 5.5mm x 45mm, Self Drilling, Variable Angle	8
GDDAB5550	Lateral Plate, Screw, 5.5mm x 50mm, Self Drilling, Variable Angle	8
GDDAB5555	Lateral Plate, Screw, 5.5mm x 55mm, Self Drilling, Variable Angle	8
GDDAB5560	Lateral Plate, Screw, 5.5mm x 60mm, Self Drilling, Variable Angle	8
GDDAB6030	Lateral Plate, Screw, 6.0mm x 30mm, Self Drilling, Variable Angle	4
GDDAB6035	Lateral Plate, Screw, 6.0mm x 35mm, Self Drilling, Variable Angle	4
GDDAB6040	Lateral Plate, Screw, 6.0mm x 40mm, Self Drilling, Variable Angle	4
GDDAB6045	Lateral Plate, Screw, 6.0mm x 45mm, Self Drilling, Variable Angle	4
GDDAB6050	Lateral Plate, Screw, 6.0mm x 50mm, Self Drilling, Variable Angle	4
GDDAB6055	Lateral Plate, Screw, 6.0mm x 55mm, Self Drilling, Variable Angle	4
GDDAB6060	Lateral Plate, Screw, 6.0mm x 60mm, Self Drilling, Variable Angle	4

RETRACTOR INSTRUMENTS

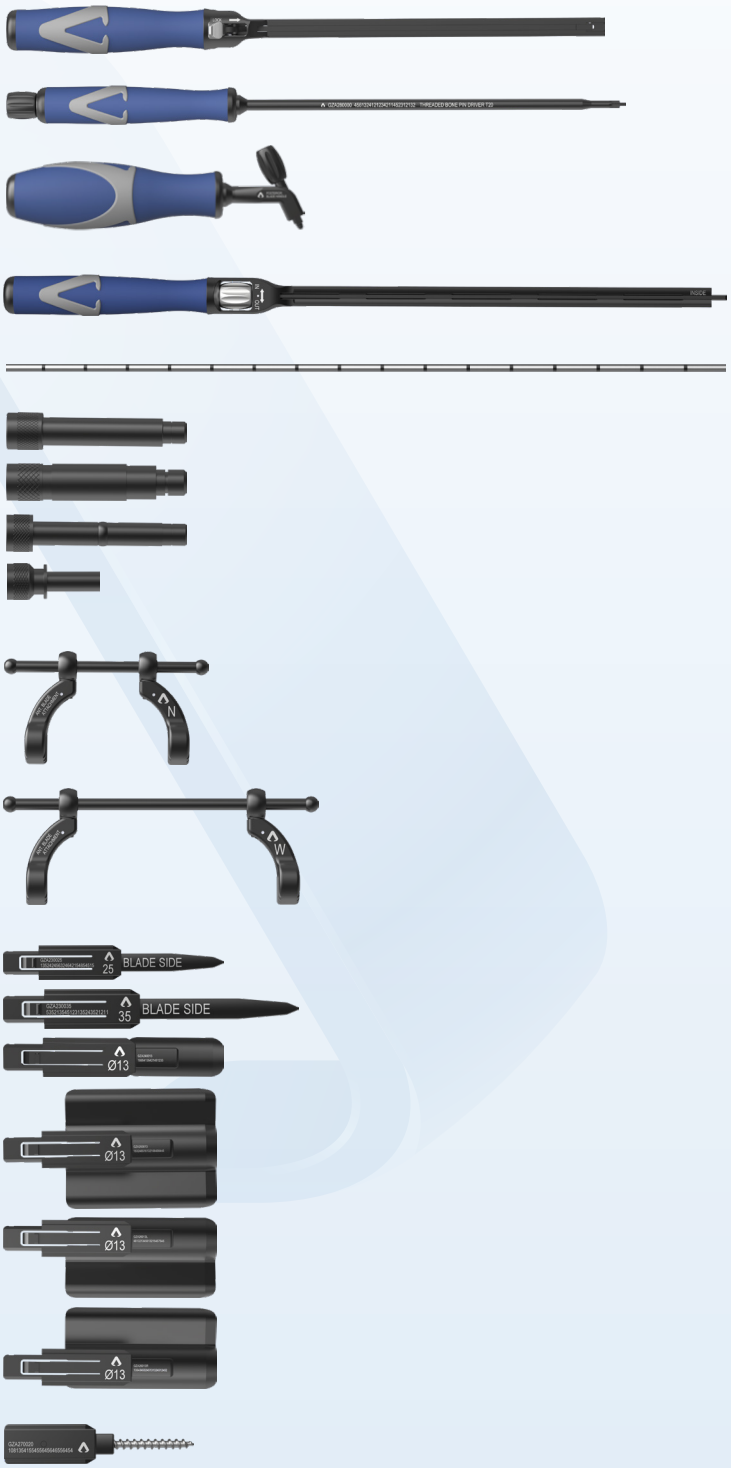
Part Number	Description	Qty	
GZA020000	Incision Locator	1	
ML-0440S	Dilator, 8mm / 13mm	1	
ML-0441S	Dilator, 8mm / 13mm, 18mm	1 / OPT	
ML-0449S	Dilator, 22mm	1 / OPT	
GZA050000	Dilator Holder	1	
302430-000-200	Ball Tip Stimulating Probe	1	
302775-200	Stimulation Clip	1	
GZA060000	Retractor	1	
1587-09	Disposable Annulotomy Knife	1	

RETRACTOR INSTRUMENTS

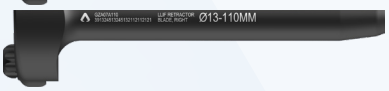
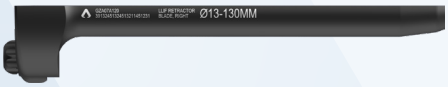
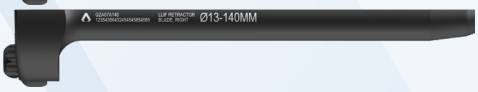
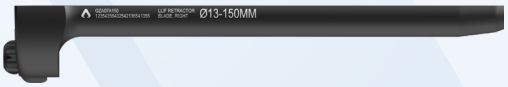
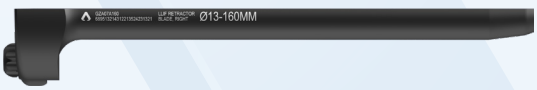
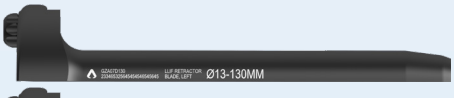
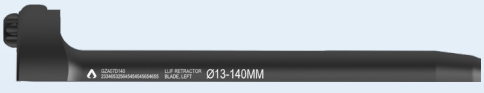
Part Number	Description	Qty
GZA090010	Anterior Blade, Short, 8mm	1
GZA090020	Anterior Blade, Long, 8mm	1
GZA090030	Anterior Blade, Short, 12mm	1
GZA090040	Anterior Blade, Long, 12mm	1
GZA130000	Retractor, Handle	1
GZA140000	Retractor, Driver	2
GZA150000	Retractor, Table Fixation Arm	1
5.750-N-VE	Universal Radial Clamp	1
GZA160002	Bifurcated Surgical Illuminator	1
12139	Lumitex Fiber Optic Cable - 4mm Universal	1

RETRACTOR INSTRUMENTS

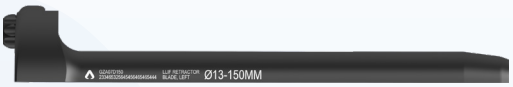
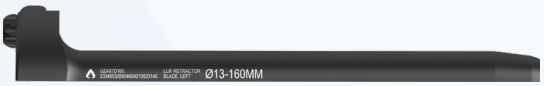
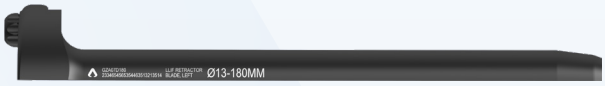
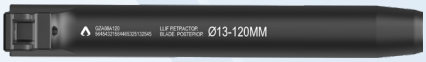
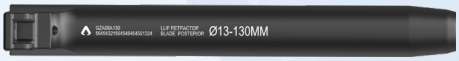
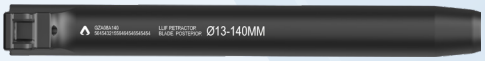
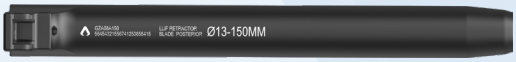
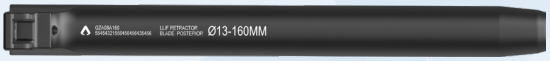
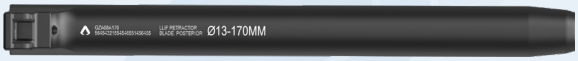
Part Number	Description	Qty
GZA220000	Retractor, Blade, Shim Inserter	1
GZA280000	Retractor, Blade, Threaded Bone Pin, Driver	1
GZA290000	Retractor, Posterior Blade Handle	1
GZA300000	Retractor, Blade, Shim Tamp	1
GZA030000	Guidewire, Blunt Tip, 1.4mm X 320mm	10
12140	Light Source Adapter, Acmi	1
12143	Light Source Adapter, Wolf	1
12141	Light Source Adapter, Olympus	1
12142	Light Source Adapter, Storz	1
GZA100010	Retractor, Anterior Blade Mount, Narrow	1
GZA100020	Retractor, Anterior Blade Mount, Wide	1
GZA230025	Retractor, Posterior Blade Shim, 25mm	1
GZA230035	Retractor, Posterior Blade Shim, 35mm	1
GZA240013	Retractor, Blade, Blade Extension Shim, Ø13	2
GZA250013	Retractor, Blade, Lateral Extension Shim, Ø13	1
GZA26013L	Retractor, Blade, Lateral Extension Shim, Left, Ø13	1
GZA26013R	Retractor, Blade, Lateral Extension Shim, Right, Ø13	1
GZA270020	Retractor, Blade, Threaded Bone Pin, 20mm	2



RETRACTOR INSTRUMENTS

Part Number	Description	Qty	
GZA07A090	Retractor, Blades, Right, 13mm x 90mm	1	
GZA07A100	Retractor, Blades, Right, 13mm x 100mm	1	
GZA07A110	Retractor, Blades, Right, 13mm x 110mm	1	
GZA07A120	Retractor, Blades, Right, 13mm x 120mm	1	
GZA07A130	Retractor, Blades, Right, 13mm x 130mm	1	
GZA07A140	Retractor, Blades, Right, 13mm x 140mm	1	
GZA07A150	Retractor, Blades, Right, 13mm x 150mm	1	
GZA07A160	Retractor, Blades, Right, 13mm x 160mm	1	
GZA07A170	Retractor, Blades, Right, 13mm x 170mm	1	
GZA07A180	Retractor, Blades, Right, 13mm x 180mm	1	
GZA07A190	Retractor, Blades, Right, 13mm x 190mm	1	
GZA07D090	Retractor, Blades, Left, 13mm x 90mm	1	
GZA07D100	Retractor, Blades, Left, 13mm x 100mm	1	
GZA07D110	Retractor, Blades, Left, 13mm x 110mm	1	
GZA07D120	Retractor, Blades, Left, 13mm x 120mm	1	
GZA07D130	Retractor, Blades, Left, 13mm x 130mm	1	
GZA07D140	Retractor, Blades, Left, 13mm x 140mm	1	

RETRACTOR INSTRUMENTS

Part Number	Description	Qty	
GZA07D150	Retractor, Blades, Left, 13mm x 150mm	1	
GZA07D160	Retractor, Blades, Left, 13mm x 160mm	1	
GZA07D170	Retractor, Blades, Left, 13mm x 170mm	1	
GZA07D180	Retractor, Blades, Left, 13mm x 180mm	1	
GZA07D190	Retractor, Blades, Left, 13mm x 190mm	1	
GZA08A090	Retractor, Blade, Posterior, 13 x 90mm	1	
GZA08A100	Retractor, Blade, Posterior, 13 x 100mm	1	
GZA08A110	Retractor, Blade, Posterior, 13 x 110mm	1	
GZA08A120	Retractor, Blade, Posterior, 13 x 120mm	1	
GZA08A130	Retractor, Blade, Posterior, 13 x 130mm	1	
GZA08A140	Retractor, Blade, Posterior, 13 x 140mm	1	
GZA08A150	Retractor, Blade, Posterior, 13 x 150mm	1	
GZA08A160	Retractor, Blade, Posterior, 13 x 160mm	1	
GZA08A170	Retractor, Blade, Posterior, 13 x 170mm	1	
GZA08A180	Retractor, Blade, Posterior, 13 x 180mm	1	
GZA08A190	Retractor, Blade, Posterior, 13 x 190mm	1	

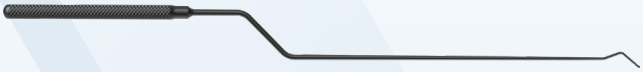
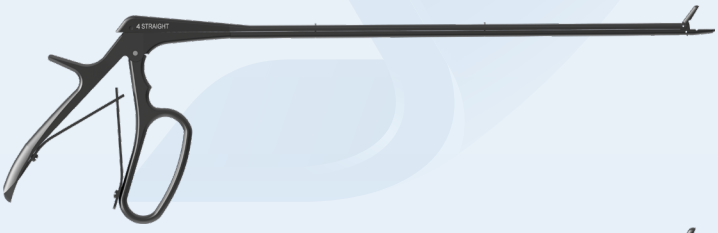
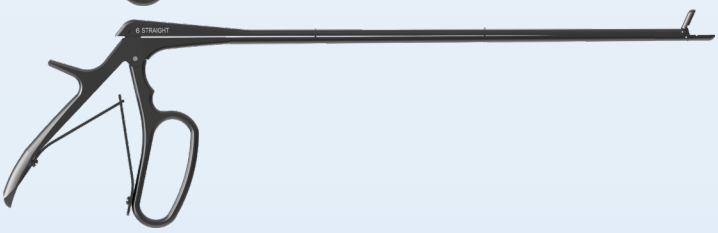
RETRACTOR INSTRUMENTS

Part Number	Description	Qty
GZA11R090	Retractor, Blades, Right, 22mm x 90mm	1
GZA11R095	Retractor, Blades, Right, 22mm x 95mm	1
GZA11R100	Retractor, Blades, Right, 22mm x 100mm	1
GZA11R110	Retractor, Blades, Right, 22mm x 110mm	1
GZA11R120	Retractor, Blades, Right, 22mm x 120mm	1
GZA11R130	Retractor, Blades, Right, 22mm x 130mm	1
GZA11R140	Retractor, Blades, Right, 22mm x 140mm	1
GZA11R150	Retractor, Blades, Right, 22mm x 150mm	1
GZA11R160	Retractor, Blades, Right, 22mm x 160mm	1
GZA11R170	Retractor, Blades, Right, 22mm x 170mm	1
GZA11R180	Retractor, Blades, Right, 22mm x 180mm	1
GZA11R190	Retractor, Blades, Right, 22mm x 190mm	1

RETRACTOR INSTRUMENTS

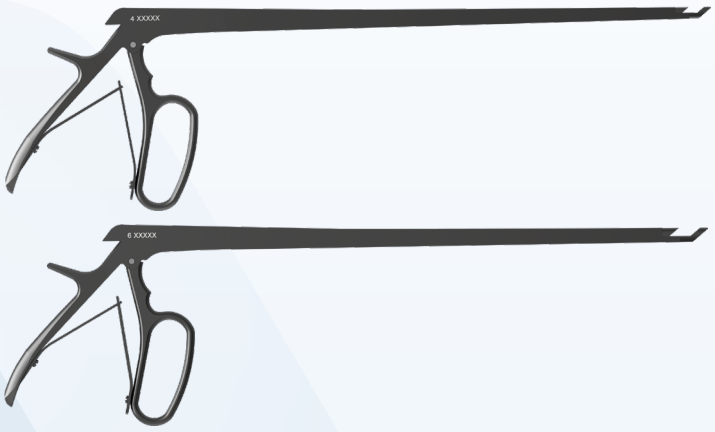
Part Number	Description	Qty
GZA11L090	Retractor, Blades, Left, 22mm x 90mm	1
GZA11L095	Retractor, Blades, Left, 22mm x 95mm	1
GZA11L100	Retractor, Blades, Left, 22mm x 100mm	1
GZA11L110	Retractor, Blades, Left, 22mm x 110mm	1
GZA11L120	Retractor, Blades, Left, 22mm x 120mm	1
GZA11L130	Retractor, Blades, Left, 22mm x 130mm	1
GZA11L140	Retractor, Blades, Left, 22mm x 140mm	1
GZA11L150	Retractor, Blades, Left, 22mm x 150mm	1
GZA11L160	Retractor, Blades, Left, 22mm x 160mm	1
GZA11L170	Retractor, Blades, Left, 22mm x 170mm	1
GZA11L180	Retractor, Blades, Left, 22mm x 180mm	1
GZA11L190	Retractor, Blades, Left, 22mm x 190mm	1

DISC PREP INSTRUMENTS

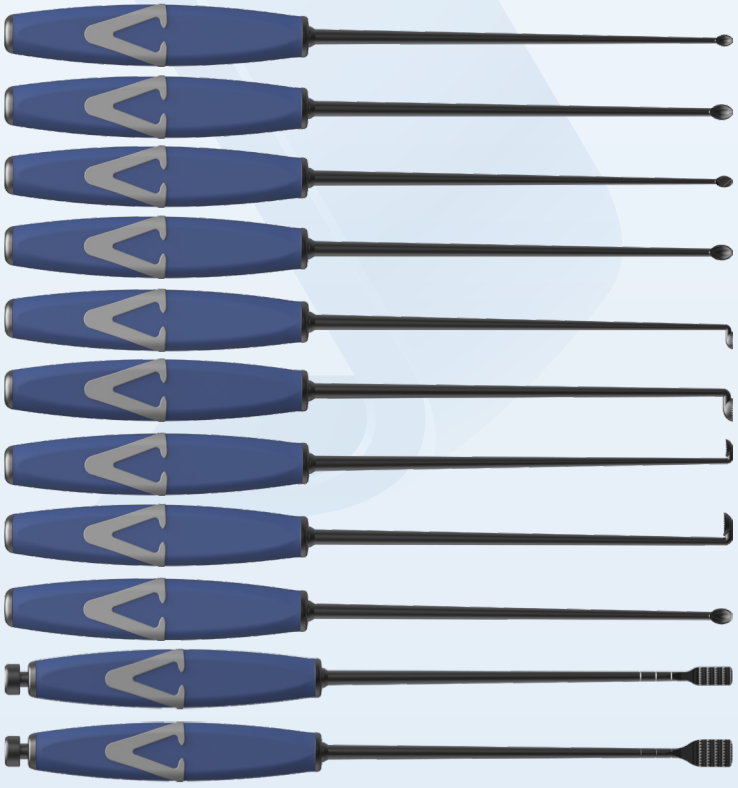
Part Number	Description	Qty	
AST-KIRWAN09	Bipolar	1	
GZB030010	Suction, 12fr, 200mm	1	
GZB040010	Penfield Push, #4	1	
GZB040020	Penfield Pull, #4	1	
GZB050000	Woodson	1	
GZB060000	Annulotomy Knife	1	
GZB09SZ12	Cobb, 12mm	1	
GZB09SZ18	Cobb, 18mm	1	
GZB24SZ04	Box Cutter, Modular, 4mm	1	
GZB24SZ06	Box Cutter, Modular, 6mm	1	
GZB24SZ08	Box Cutter, Modular, 8mm	1	
GZB11SQ04	Pituitary, Straight, Serrated, #4	1	
GZB11SQ06	Pituitary, Straight, Serrated, #6	1	

DISC PREP INSTRUMENTS

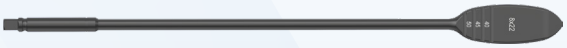
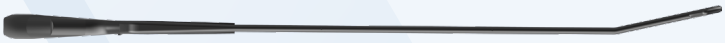
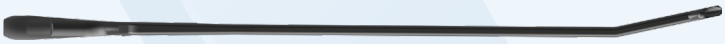
Part Number	Description	Qty
GZB12SZ04	Kerrison, Straight, #4	1
GZB12SZ06	Kerrison, Straight, #6	1



GZB13S104	Cup Curette, Up, 10°, Serrated, #4	1
GZB13S106	Cup Curette, Up, 10°, Serrated, #6	1
GZB13SQ04	Cup Curette, Serrated, #4	1
GZB13SQ06	Cup Curette, Serrated, #6	1
GZB13SV04	Cup Curette, Down, 90°, Serrated, #4	1
GZB13SV06	Cup Curette, Down, 90°, Serrated, #6	1
GZB13SY04	Cup Curette, Up, 90°, Serrated, #4	1
GZB13SY06	Cup Curette, Up, 90°, Serrated, #6	1
GZB15SZ06	Stirrup Curette, #6	1
GZB16SR12	Rasp, Double Sided,12mm	1
GZB16SR18	Rasp, Double Sided,18mm	1



DISC PREP INSTRUMENTS

Part Number	Description	Qty	
GZB25SZ01	Distractor, Modular, 4mm x 16mm	1	
GZB25SZ02	Distractor, Modular, 6mm x 18mm	1	
GZB25SZ03	Distractor, Modular, 8mm x 18mm	1	
GZB25SZ05	Distractor, Modular, 8mm x 22mm	1	
GZB25SZ08	Distractor, Modular, 10mm x 22mm	1	
GZB11AM04	Pituitary, Angled, High, Left, Serrated, #4	1	
GZB11AM06	Pituitary, Angled, High, Left, Serrated, #6	1	
GZB11AN04	Pituitary, Angled, High, Right, Serrated, #4	1	
GZB11AN06	Pituitary, Angled, High, Right, Serrated, #6	1	
GZB13AK04	Cup Curette, Angled, Low, Cranial, Serrated, #4	1	
GZB13AK06	Cup Curette, Angled, Low, Cranial, Serrated, #6	1	
GZB13AL04	Cup Curette, Angled, Low, Caudal, Serrated, #4	1	
GZB13AL06	Cup Curette, Angled, Low, Caudal, Serrated, #6	1	
GZB13AM04	Cup Curette, Angled, High, Cranial, Serrated, #4	1	
GZB13AM06	Cup Curette, Angled, High, Cranial, Serrated, #6	1	
GZB13AN04	Cup Curette, Angled, High, Caudal, Serrated, #4	1	
GZB13AN06	Cup Curette, Angled, High, Caudal, Serrated, #6	1	

DISC PREP INSTRUMENTS

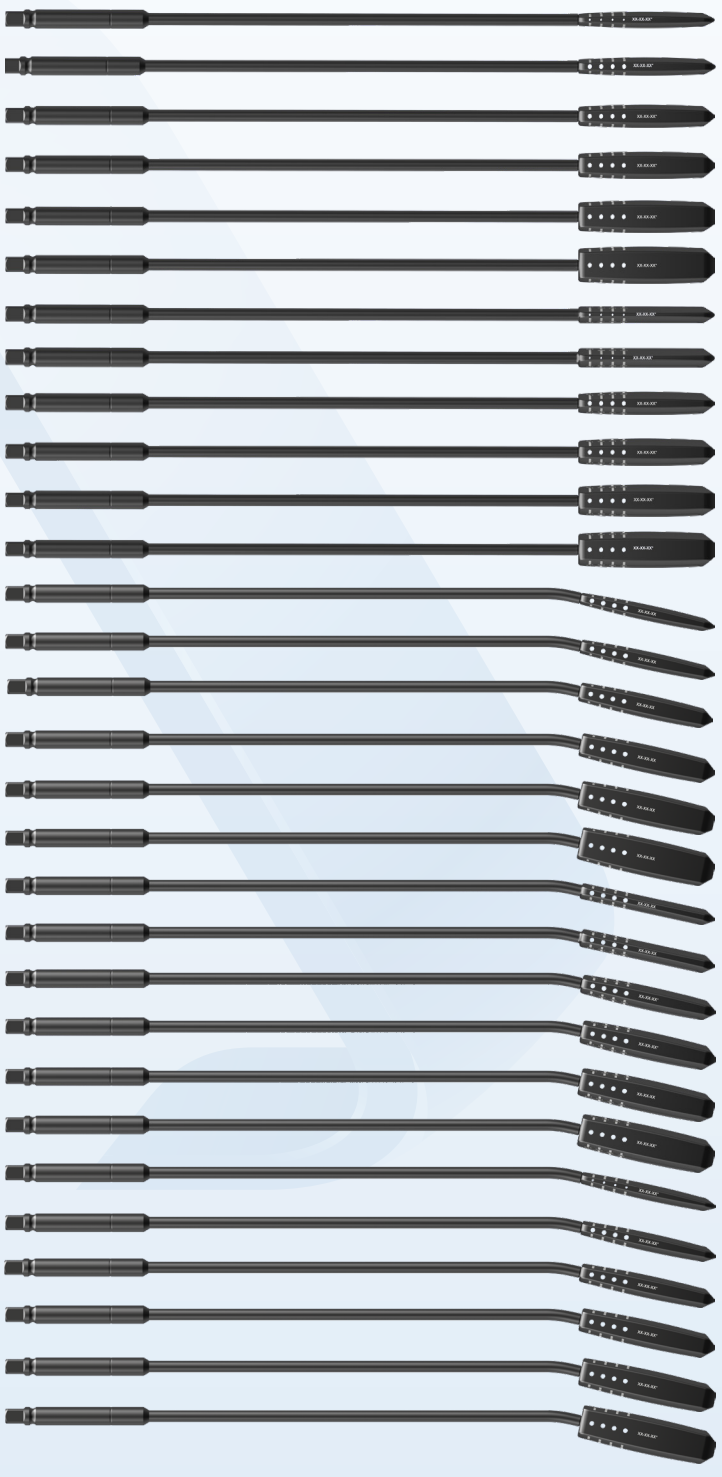
Part Number	Description	Qty	
GZB24AB04	Box Cutter, Modular, Angled, 4mm	1	
GZB24AB06	Box Cutter, Modular, Angled, 6mm	1	
GZB24AB08	Box Cutter, Modular, Angled, 8mm	1	
GZB09AC12	Cobb, Angled, Low, Cranial, 12mm	1	
GZB09AC18	Cobb, Angled, Low, Cranial, 18mm	1	
GZB09AD12	Cobb, Angled, Low, Caudal, 12mm	1	
GZB09AD18	Cobb, Angled, Low, Caudal, 18mm	1	
GZB09AE12	Cobb, Angled, High, Cranial,12mm	1	
GZB09AE18	Cobb, Angled, High, Cranial,18mm	1	
GZB09AF12	Cobb, Angled, High, Caudal,12mm	1	
GZB09AF18	Cobb, Angled, High, Caudal, 18mm	1	
GZB15AC06	Stirrup Curette, Angled, Low, Cranial, #6	1	
GZB15AD06	Stirrup Curette, Angled, Low, Caudal, #6	1	
GZB15AE06	Stirrup Curette, Angled, High, Cranial, #6	1	
GZB15AF06	Stirrup Curette, Angled, High, Caudal, #6	1	
GZB16AA18	Rasp, Angled, Low, Double Sided, 18mm	1	
GZB16AB18	Rasp, Angled, High, Double Sided, 18mm	1	
GZB25AB01	Distractor, Modular, Angled, 4mm X 16mm	1	
GZB25AB02	Distractor, Modular, Angled, 6mm X 18mm	1	
GZB25AB03	Distractor, Modular, Angled, 8mm X 18mm	1	
GZB25AB05	Distractor, Modular, Angled, 8mm X 22mm	1	
GZB25AB08	Distractor, Modular, Angled, 10mm X 22mm	1	

IMPLANT SPECIFIC INSTRUMENTS

Part Number	Description	Qty
EAFGABXFZ	Axial, Medium Long, Advanced Ext 1/4" Sq, S/L Slap Hammer Cap	2
EBEGABAFZ	T Handle, Advanced Ext 1/4" Sq, S/L Slap Hammer Cap	1
GZC040000	Inserter, Straight	2
GZC040007	Inserter, Straight, 7mm	1
GZC040010	Inserter, Angled	1
GZC0400A7	Inserter, Angled, 7mm	1
GZC060000	Graft Retention Shim	2
GZC070000	Tamp	1
GZC120000	Tamp, Angled	1
GZC080000	Mallet	1
GZC090000	Slaphammer	1
GZC01A07B	Trial, Modular, 18mm X 7mm X 7°	1 / OPT
GZC01A08B	Trial, Modular, 18mm X 8mm X 7°	1 / OPT
GZC01A10B	Trial, Modular, 18mm X 10mm X 7°	1 / OPT
GZC01A12B	Trial, Modular, 18mm X 12mm X 7°	1 / OPT
GZC01A14B	Trial, Modular, 18mm X 14mm X 7°	1 / OPT
GZC01A16B	Trial, Modular, 18mm X 16mm X 7°	1 / OPT
GZC01A07C	Trial, Modular, 18mm X 7mm X 12°	1 / OPT
GZC01A08D	Trial, Modular, 18mm X 8mm X 15°	1 / OPT
GZC01A10D	Trial, Modular, 18mm X 10mm X 15°	1 / OPT
GZC01A12D	Trial, Modular, 18mm X 12mm X 15°	1 / OPT
GZC01A14D	Trial, Modular, 18mm X 14mm X 15°	1 / OPT
GZC01A16D	Trial, Modular, 18mm X 16mm X 15°	1 / OPT

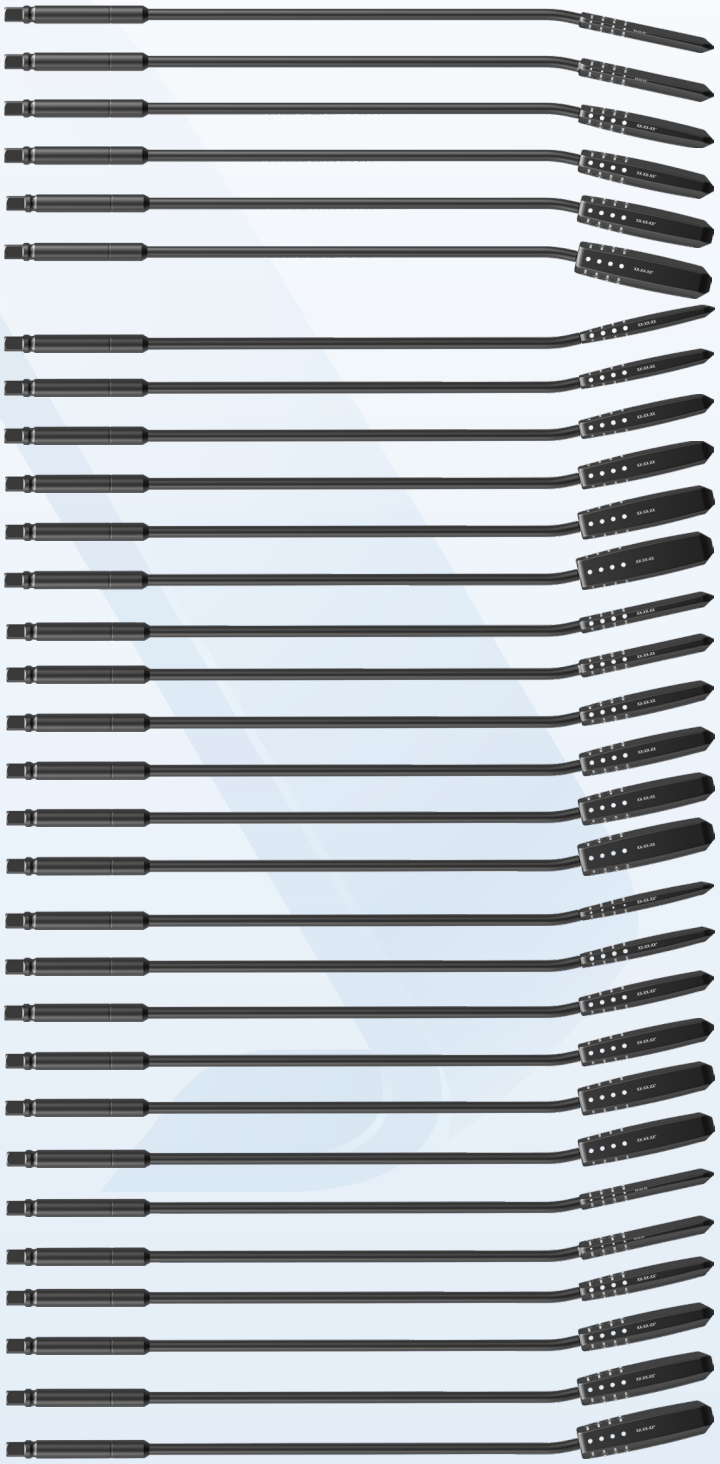
IMPLANT SEPECIFIC INSTRUMENTS

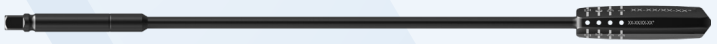
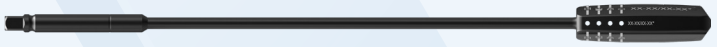
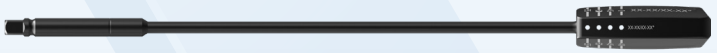
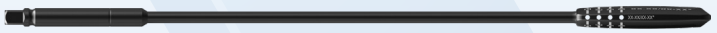
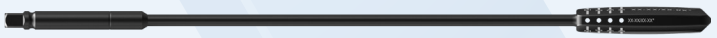
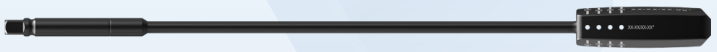
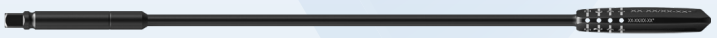
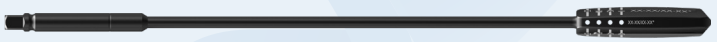
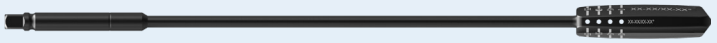
Part Number	Description	Qty
GZC01C07B	Trial, Modular, 22mm x 7mm x 7°	1 / OPT
GZC01C08B	Trial, Modular, 22mm x 8mm x 7°	1 / OPT
GZC01C10B	Trial, Modular, 22mm x 10mm x 7°	1 / OPT
GZC01C12B	Trial, Modular, 22mm x 12mm x 7°	1 / OPT
GZC01C14B	Trial, Modular, 22mm x 14mm x 7°	1 / OPT
GZC01C16B	Trial, Modular, 22mm x 16mm x 7°	1 / OPT
GZC01C07C	Trial, Modular, 22mm x 7mm x 12°	1 / OPT
GZC01C08D	Trial, Modular, 22mm x 8mm x 15°	1 / OPT
GZC01C10D	Trial, Modular, 22mm x 10mm x 15°	1 / OPT
GZC01C12D	Trial, Modular, 22mm x 12mm x 15°	1 / OPT
GZC01C14D	Trial, Modular, 22mm x 14mm x 15°	1 / OPT
GZC01C16D	Trial, Modular, 22mm x 16mm x 15°	1 / OPT
GZC11A07B	Trial, Modular, Angled Right, 18mm x 7mm x 7°	1 / OPT
GZC11A08B	Trial, Modular, Angled Right, 18mm x 8mm x 7°	1 / OPT
GZC11A10B	Trial, Modular, Angled Right, 18mm x 10mm x 7°	1 / OPT
GZC11A12B	Trial, Modular, Angled Right, 18mm x 12mm x 7°	1 / OPT
GZC11A14B	Trial, Modular, Angled Right, 18mm x 14mm x 7°	1 / OPT
GZC11A16B	Trial, Modular, Angled Right, 18mm x 16mm x 7°	1 / OPT
GZC11A07C	Trial, Modular, Angled Right, 18mm x 7mm x 12°	1 / OPT
GZC11A08D	Trial, Modular, Angled Right, 18mm x 8mm x 15°	1 / OPT
GZC11A10D	Trial, Modular, Angled Right, 18mm x 10mm x 15°	1 / OPT
GZC11A12D	Trial, Modular, Angled Right, 18mm x 12mm x 15°	1 / OPT
GZC11A14D	Trial, Modular, Angled Right, 18mm x 14mm x 15°	1 / OPT
GZC11A16D	Trial, Modular, Angled Right, 18mm x 16mm x 15°	1 / OPT
GZC11C07B	Trial, Modular, Angled Right, 22mm x 7mm x 7°	1 / OPT
GZC11C08B	Trial, Modular, Angled Right, 22mm x 8mm x 7°	1 / OPT
GZC11C10B	Trial, Modular, Angled Right, 22mm x 10mm x 7°	1 / OPT
GZC11C12B	Trial, Modular, Angled Right, 22mm x 12mm x 7°	1 / OPT
GZC11C14B	Trial, Modular, Angled Right, 22mm x 14mm x 7°	1 / OPT
GZC11C16B	Trial, Modular, Angled Right, 22mm x 16mm x 7°	1 / OPT



IMPLANT SEPECIFIC INSTRUMENTS

Part Number	Description	Qty
GZC11C07C	Trial, Modular, Angled Right, 22mm x 7mm x 12°	1 / OPT
GZC11C08D	Trial, Modular, Angled Right, 22mm x 8mm x 15°	1 / OPT
GZC11C10D	Trial, Modular, Angled Right, 22mm x 10mm x 15°	1 / OPT
GZC11C12D	Trial, Modular, Angled Right, 22mm x 12mm x 15°	1 / OPT
GZC11C14D	Trial, Modular, Angled Right, 22mm x 14mm x 15°	1 / OPT
GZC11C16D	Trial, Modular, Angled Right, 22mm x 16mm x 15°	1 / OPT
GZC10A07B	Trial, Modular, Angled Left, 18mm x 7mm x 7°	1 / OPT
GZC10A08B	Trial, Modular, Angled Left, 18mm x 8mm x 7°	1 / OPT
GZC10A10B	Trial, Modular, Angled Left, 18mm x 10mm x 7°	1 / OPT
GZC10A12B	Trial, Modular, Angled Left, 18mm x 12mm x 7°	1 / OPT
GZC10A14B	Trial, Modular, Angled Left, 18mm x 14mm x 7°	1 / OPT
GZC10A16B	Trial, Modular, Angled Left, 18mm x 16mm x 7°	1 / OPT
GZC10A07C	Trial, Modular, Angled Left, 18mm x 7mm x 12°	1 / OPT
GZC10A08D	Trial, Modular, Angled Left, 18mm x 8mm x 15°	1 / OPT
GZC10A10D	Trial, Modular, Angled Left, 18mm x 10mm x 15°	1 / OPT
GZC10A12D	Trial, Modular, Angled Left, 18mm x 12mm x 15°	1 / OPT
GZC10A14D	Trial, Modular, Angled Left, 18mm x 14mm x 15°	1 / OPT
GZC10A16D	Trial, Modular, Angled Left, 18mm x 16mm x 15°	1 / OPT
GZC10C07B	Trial, Modular, Angled Left, 22mm x 7mm x 7°	1 / OPT
GZC10C08B	Trial, Modular, Angled Left, 22mm x 8mm x 7°	1 / OPT
GZC10C10B	Trial, Modular, Angled Left, 22mm x 10mm x 7°	1 / OPT
GZC10C12B	Trial, Modular, Angled Left, 22mm x 12mm x 7°	1 / OPT
GZC10C14B	Trial, Modular, Angled Left, 22mm x 14mm x 7°	1 / OPT
GZC10C16B	Trial, Modular, Angled Left, 22mm x 16mm x 7°	1 / OPT
GZC10C07C	Trial, Modular, Angled Left, 22mm x 7mm x 12°	1 / OPT
GZC10C08D	Trial, Modular, Angled Left, 22mm x 8mm x 15°	1 / OPT
GZC10C10D	Trial, Modular, Angled Left, 22mm x 10mm x 15°	1 / OPT
GZC10C12D	Trial, Modular, Angled Left, 22mm x 12mm x 15°	1 / OPT
GZC10C14D	Trial, Modular, Angled Left, 22mm x 14mm x 15°	1 / OPT
GZC10C16D	Trial, Modular, Angled Left, 22mm x 16mm x 15°	1 / OPT



Part Number	Description	Qty	
GZC01A02E	TRIAL, MODULAR, STRAIGHT, 18MM X 02MM/10MM X 20°	1 / OPT	
GZC01A04E	TRIAL, MODULAR, STRAIGHT, 18MM X 04MM/12MM X 20°	1 / OPT	
GZC01A06E	TRIAL, MODULAR, STRAIGHT, 18MM X 06MM/14MM X 20°	1 / OPT	
GZC01A08E	TRIAL, MODULAR, STRAIGHT, 18MM X 08MM/16MM X 20°	1 / OPT	
GZC01A10E	TRIAL, MODULAR, STRAIGHT, 18MM X 10MM/18MM X 20°	1 / OPT	
GZC01A02F	TRIAL, MODULAR, STRAIGHT, 18MM X 02MM/11MM X 25°	1 / OPT	
GZC01A04F	TRIAL, MODULAR, STRAIGHT, 18MM X 04MM/13MM X 25°	1 / OPT	
GZC01A06F	TRIAL, MODULAR, STRAIGHT, 18MM X 06MM/15MM X 25°	1 / OPT	
GZC01A08F	TRIAL, MODULAR, STRAIGHT, 18MM X 08MM/17MM X 25°	1 / OPT	
GZC01A10F	TRIAL, MODULAR, STRAIGHT, 18MM X 10MM/19MM X 25°	1 / OPT	
GZC01A02G	TRIAL, MODULAR, STRAIGHT, 18MM X 02MM/13MM X 30°	1 / OPT	
GZC01A04G	TRIAL, MODULAR, STRAIGHT, 18MM X 04MM/15MM X 30°	1 / OPT	
GZC01A06G	TRIAL, MODULAR, STRAIGHT, 18MM X 06MM/17MM X 30°	1 / OPT	
GZC01A08G	TRIAL, MODULAR, STRAIGHT, 18MM X 08MM/19MM X 30°	1 / OPT	
GZC01A10G	TRIAL, MODULAR, STRAIGHT, 18MM X 10MM/21MM X 30°	1 / OPT	
GZC01C02E	TRIAL, MODULAR, STRAIGHT, 22MM X 02MM/11MM X 20°	1 / OPT	
GZC01C04E	TRIAL, MODULAR, STRAIGHT, 22MM X 04MM/13MM X 20°	1 / OPT	
GZC01C06E	TRIAL, MODULAR, STRAIGHT, 22MM X 06MM/15MM X 20°	1 / OPT	
GZC01C08E	TRIAL, MODULAR, STRAIGHT, 22MM X 08MM/17MM X 20°	1 / OPT	
GZC01C10E	TRIAL, MODULAR, STRAIGHT, 22MM X 10MM/19MM X 20°	1 / OPT	
GZC01C02F	TRIAL, MODULAR, STRAIGHT, 22MM X 02MM/13MM X 25°	1 / OPT	
GZC01C04F	TRIAL, MODULAR, STRAIGHT, 22MM X 04MM/15MM X 25°	1 / OPT	
GZC01C06F	TRIAL, MODULAR, STRAIGHT, 22MM X 06MM/17MM X 25°	1 / OPT	
GZC01C08F	TRIAL, MODULAR, STRAIGHT, 22MM X 08MM/19MM X 25°	1 / OPT	
GZC01C10F	TRIAL, MODULAR, STRAIGHT, 22MM X 10MM/21MM X 25°	1 / OPT	
GZC01C02G	TRIAL, MODULAR, STRAIGHT, 22MM X 02MM/15MM X 30°	1 / OPT	
GZC01C04G	TRIAL, MODULAR, STRAIGHT, 22MM X 04MM/17MM X 30°	1 / OPT	
GZC01C06G	TRIAL, MODULAR, STRAIGHT, 22MM X 06MM/19MM X 30°	1 / OPT	
GZC01C08G	TRIAL, MODULAR, STRAIGHT, 22MM X 08MM/21MM X 30°	1 / OPT	
GZC01C10G	TRIAL, MODULAR, STRAIGHT, 22MM X 10MM/23MM X 30°	1 / OPT	

Part Number	Description	Qty
GZC10A02E	TRIAL, MODULAR, ANGLED LEFT, 18MM X 02MM/10MM X 20°	1 / OPT
GZC10A04E	TRIAL, MODULAR, ANGLED LEFT, 18MM X 04MM/12MM X 20°	1 / OPT
GZC10A06E	TRIAL, MODULAR, ANGLED LEFT, 18MM X 06MM/14MM X 20°	1 / OPT
GZC10A08E	TRIAL, MODULAR, ANGLED LEFT, 18MM X 08MM/16MM X 20°	1 / OPT
GZC10A10E	TRIAL, MODULAR, ANGLED LEFT, 18MM X 10MM/18MM X 20°	1 / OPT
GZC10A02F	TRIAL, MODULAR, ANGLED LEFT, 18MM X 02MM/11MM X 25°	1 / OPT
GZC10A04F	TRIAL, MODULAR, ANGLED LEFT, 18MM X 04MM/13MM X 25°	1 / OPT
GZC10A06F	TRIAL, MODULAR, ANGLED LEFT, 18MM X 06MM/15MM X 25°	1 / OPT
GZC10A08F	TRIAL, MODULAR, ANGLED LEFT, 18MM X 08MM/17MM X 25°	1 / OPT
GZC10A10F	TRIAL, MODULAR, ANGLED LEFT, 18MM X 10MM/19MM X 25°	1 / OPT
GZC10A02G	TRIAL, MODULAR, ANGLED LEFT, 18MM X 02MM/13MM X 30°	1 / OPT
GZC10A04G	TRIAL, MODULAR, ANGLED LEFT, 18MM X 04MM/15MM X 30°	1 / OPT
GZC10A06G	TRIAL, MODULAR, ANGLED LEFT, 18MM X 06MM/17MM X 30°	1 / OPT
GZC10A08G	TRIAL, MODULAR, ANGLED LEFT, 18MM X 08MM/19MM X 30°	1 / OPT
GZC10A10G	TRIAL, MODULAR, ANGLED LEFT, 18MM X 10MM/21MM X 30°	1 / OPT
GZC10C02E	TRIAL, MODULAR, ANGLED LEFT, 22MM X 02MM/11MM X 20°	1 / OPT
GZC10C04E	TRIAL, MODULAR, ANGLED LEFT, 22MM X 04MM/13MM X 20°	1 / OPT
GZC10C06E	TRIAL, MODULAR, ANGLED LEFT, 22MM X 06MM/15MM X 20°	1 / OPT
GZC10C08E	TRIAL, MODULAR, ANGLED LEFT, 22MM X 08MM/17MM X 20°	1 / OPT
GZC10C10E	TRIAL, MODULAR, ANGLED LEFT, 22MM X 10MM/19MM X 20°	1 / OPT
GZC10C02F	TRIAL, MODULAR, ANGLED LEFT, 22MM X 02MM/13MM X 25°	1 / OPT
GZC10C04F	TRIAL, MODULAR, ANGLED LEFT, 22MM X 04MM/15MM X 25°	1 / OPT
GZC10C06F	TRIAL, MODULAR, ANGLED LEFT, 22MM X 06MM/17MM X 25°	1 / OPT
GZC10C08F	TRIAL, MODULAR, ANGLED LEFT, 22MM X 08MM/19MM X 25°	1 / OPT
GZC10C10F	TRIAL, MODULAR, ANGLED LEFT, 22MM X 10MM/21MM X 25°	1 / OPT
GZC10C02G	TRIAL, MODULAR, ANGLED LEFT, 22MM X 02MM/15MM X 30°	1 / OPT
GZC10C04G	TRIAL, MODULAR, ANGLED LEFT, 22MM X 04MM/17MM X 30°	1 / OPT
GZC10C06G	TRIAL, MODULAR, ANGLED LEFT, 22MM X 06MM/19MM X 30°	1 / OPT
GZC10C08G	TRIAL, MODULAR, ANGLED LEFT, 22MM X 08MM/21MM X 30°	1 / OPT
GZC10C10G	TRIAL, MODULAR, ANGLED LEFT, 22MM X 10MM/23MM X 30°	1 / OPT

Part Number	Description	Qty
GZC11A02E	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 02MM/10MM X 20°	1 / OPT
GZC11A04E	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 04MM/12MM X 20°	1 / OPT
GZC11A06E	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 06MM/14MM X 20°	1 / OPT
GZC11A08E	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 08MM/16MM X 20°	1 / OPT
GZC11A10E	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 10MM/18MM X 20°	1 / OPT
GZC11A02F	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 02MM/11MM X 25°	1 / OPT
GZC11A04F	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 04MM/13MM X 25°	1 / OPT
GZC11A06F	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 06MM/15MM X 25°	1 / OPT
GZC11A08F	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 08MM/17MM X 25°	1 / OPT
GZC11A10F	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 10MM/19MM X 25°	1 / OPT
GZC11A02G	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 02MM/13MM X 30°	1 / OPT
GZC11A04G	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 04MM/15MM X 30°	1 / OPT
GZC11A06G	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 06MM/17MM X 30°	1 / OPT
GZC11A08G	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 08MM/19MM X 30°	1 / OPT
GZC11A10G	TRIAL, MODULAR, ANGLED RIGHT, 18MM X 10MM/21MM X 30°	1 / OPT
GZC11C02E	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 02MM/11MM X 20°	1 / OPT
GZC11C04E	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 04MM/13MM X 20°	1 / OPT
GZC11C06E	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 06MM/15MM X 20°	1 / OPT
GZC11C08E	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 08MM/17MM X 20°	1 / OPT
GZC11C10E	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 10MM/19MM X 20°	1 / OPT
GZC11C02F	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 02MM/13MM X 25°	1 / OPT
GZC11C04F	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 04MM/15MM X 25°	1 / OPT
GZC11C06F	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 06MM/17MM X 25°	1 / OPT
GZC11C08F	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 08MM/19MM X 25°	1 / OPT
GZC11C10F	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 10MM/21MM X 25°	1 / OPT
GZC11C02G	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 02MM/15MM X 30°	1 / OPT
GZC11C04G	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 04MM/17MM X 30°	1 / OPT
GZC11C06G	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 06MM/19MM X 30°	1 / OPT
GZC11C08G	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 08MM/21MM X 30°	1 / OPT
GZC11C10G	TRIAL, MODULAR, ANGLED RIGHT, 22MM X 10MM/23MM X 30°	1 / OPT

FIXATION INSTRUMENTS

Part Number	Description	Qty
EAECDUBBZ	Axial, Large, 1/4" Sq. Ratchet	2
EDDEATAAZ	Egg Handle, AO	1
GZC040020	Plate Inserter	1
GZC040030	Angled Plate Inserter	1
GZC040020-05	Plate Inserter, Torque Driver, T15	2
GZD020010	Variable Angle Adjustable Depth Drill	1
GZD030010	Variable Angle Adjustable Depth Awl	1
GZD040050	Variable Angle Adjustable Depth Tap, Ø5.5mm	1
GZD050000	Screwdriver, T25	2
GZD060000	Screw Remover, T25	1
GZD070000	Lock Driver, T8	2
GZD080000	Plate Bolt Torque Driver, T15	2
GZD090000	Fixed Angle Driver	1
GZD130000	Angled Spring Loaded Awl	1
EDECGAAZB	Torque-Limiting Handle	1
GZD100020	Fixed Angle Drill, Bit 20mm	1
GZD110050	Fixed Angle Tap, 5.5mm	1
GZD120010	Fixed Angle Screwdriver, Bit, T25	2
GZD120020	Fixed Angle Lock Driver, Bit, T8	2

SIRION
LATERAL LUMBAR INTERBODY FUSION

INSTRUCTIONS FOR USE

1.0 DESCRIPTION: The SIRION intervertebral body fusion device is used to maintain disc space distraction in skeletally mature adults requiring an intervertebral body fusion. It is designed to be used in conjunction with supplemental spinal fixation instrumentation. The implant is available in a range of footprints and heights to suit each individual's pathology and anatomical conditions of the patient. The implant has a hollow center to allow placement of autogenous bone graft to promote intervertebral body fusion. Ridges on the superior and inferior surfaces of the device help to grip the endplates and prevent implant migration and/or expulsion.

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 SIRION SYSTEM must not be reused under any circumstances. The SIRION SYSTEM is not a stand-alone device and must be utilized in conjunction with supplemental posterior fixation. These instructions for use are designed to assist in use of the SIRION SYSTEM and are not a reference for surgical techniques.

4.0 INDICATIONS: The SIRION Lateral Lumbar Interbody System Spacer, either used individually or assembled to the SIRION plate, 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). SIRION Spacers are to be used with autogenous bone graft and supplemental fixation. Approved supplemental fixation includes the Olympic Posterior Spinal Fixation System. Patients should have at least six (6) months of non-operative treatment prior to treatment with an intervertebral cage.

The SIRION Lateral Lumbar Interbody System Plate, in 2-hole and 4-hole configurations, is indicated for use via a lateral or anterolateral surgical approach above the bifurcation of the great vessels in the treatment of thoracic and thoracolumbar (T1-L5) spine instability or via the anterior surgical approach, below the bifurcation of the great vessels in the treatment of lumbar and lumbosacral (L1-S1) spine instability as a result of: fracture (including dislocation and subluxation), tumor, degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies), scoliosis, kyphosis, lordosis, spinal stenosis, or a failed previous spine surgery.

The SIRION Lateral Lumbar Interbody System Plate, 1-hole buttress configuration is intended for use in conjunction with traditional supplemental fixation to maintain the relative position of interbody spacers during spinal fusion. The 1-hole plate is not intended for use in load-bearing applications.

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 devel opment 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 orfunction.
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 SIRION 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 SIRION 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 SIRION 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 SIRION SYSTEM has not been evaluated for safety and compatibility in the MR environment. The SIRION SYSTEM has not been tested for heating or migration in the MR environment.The safety of SIRION 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. SIRION 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.
9.6 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 SIRION 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 SIRION 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 SIRION 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 SIRION 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 eposed 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:

Metho	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. 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.

It has not beendetermined if reprocessing affects the chemical, phase, or structural properties of the hydroxyapatite on the SIRION 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 SIRION SYSTEM component(s) ever malfunctions, ASTURA MEDICAL or its representative must be notified immediately. If any SIRION 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

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