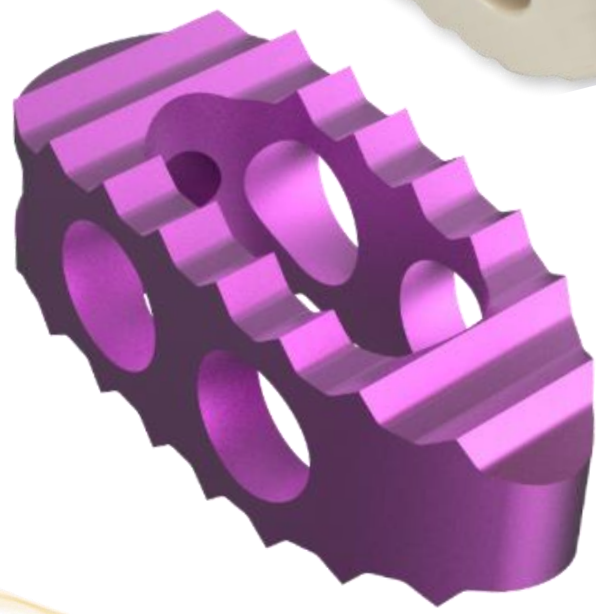




SURGICAL TECHNIQUE

PRECISION  SPINE
SHURFIT[®]
PLIF INTERBODY CAGES



PRECISION  SPINE[®]
Discover the Difference



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SHURFIT® PLIF SYSTEM OVERVIEW

The ShurFit® Posterior Lumbar Interbody Fusion System (PLIF) consists of implants with various widths, heights and lengths to accommodate individual patient anatomy and graft material size. It is to be packed with autogenous bone graft to facilitate fusion. The device is intended to provide mechanical support to the implanted level until biologic fusion is achieved. All components are manufactured from Ti-6Al-4V titanium alloy (ASTM F136) or medical grade polyetheretherketone (PEEK, per ASTM F2026) and Tantalum (ASTM F560). The products are supplied clean and "NON-STERILE".

Product Highlights:

- Large graft area provides generous biological coverage
- Convex and Lordotic (Available in 5°, 10° & 15°) Series
- Bulleted nose helps facilitate insertion

Indications:

The ShurFit Interbody Fusion Devices are indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space for the ALIF, LLIF, TLIF and T-PLIF system. Two devices are used per intervertebral space for the PLIF system.

The ShurFit Interbody Fusion Devices (ALIF, LLIF, TLIF, T-PLIF and PLIF Systems) are intended for use at either one level or two contiguous levels in the lumbar spine, from L2 to S1, for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The lumbar device is to be used with supplemental fixation and autogenous autograft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.

Please refer to package insert (LBL-IFU-002) for complete system description, indications and warnings.

PLIF Convex



PLIF Wide 5°



PLIF Wide 10°



PLIF Wide 15°



PLIF Convex Ti
(Not CE)

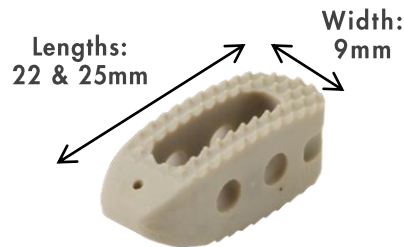


PRODUCT SUMMARY

PLIF Convex Cages (PEEK)

Features

- Aggressive Tooth Pattern to Prevent Retropulsion
- Large Graft Window
- Length: 22 & 25mm
- Height: 8-16mm (1mm increments)
- Width: 9mm



PLIF Convex 0° Sizers (Monolithic)



PLIF Convex 0° Paddle Shavers (Modular)



PLIF Convex 0° Paddle Distractors (Modular)

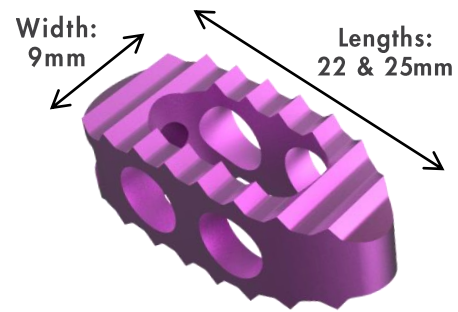


PLIF Convex Cages (Titanium)

BY REQUEST ONLY (Not CE)

Features

- Aggressive Tooth Pattern to Prevent Retropulsion
- Large Graft Window
- Length: 22 & 25mm
- Height: 8-16mm (1mm increments)
- Width: 9mm



#	Item No.	Description
1	PLIF22-08	PLIF Convex 0° Cage, Ti 8mm x 22mm
2	PLIF22-09	PLIF Convex 0° Cage, Ti 9mm x 22mm
3	PLIF22-10	PLIF Convex 0° Cage, Ti 10mm x 22mm
4	PLIF22-11	PLIF Convex 0° Cage, Ti 11mm x 22mm
5	PLIF22-12	PLIF Convex 0° Cage, Ti 12mm x 22mm
6	PLIF22-13	PLIF Convex 0° Cage, Ti 13mm x 22mm
7	PLIF22-14	PLIF Convex 0° Cage, Ti 14mm x 22mm
8	PLIF22-15	PLIF Convex 0° Cage, Ti 15mm x 22mm
9	PLIF22-16	PLIF Convex 0° Cage, Ti 16mm x 22mm

#	Item No.	Description
1	PLIF25-08	PLIF Convex 0° Cage, Ti 8mm x 25mm
2	PLIF25-09	PLIF Convex 0° Cage, Ti 9mm x 25mm
3	PLIF25-10	PLIF Convex 0° Cage, Ti 10mm x 25mm
4	PLIF25-11	PLIF Convex 0° Cage, Ti 11mm x 25mm
5	PLIF25-12	PLIF Convex 0° Cage, Ti 12mm x 25mm
6	PLIF25-13	PLIF Convex 0° Cage, Ti 13mm x 25mm
7	PLIF25-14	PLIF Convex 0° Cage, Ti 14mm x 25mm
8	PLIF25-15	PLIF Convex 0° Cage, Ti 15mm x 25mm
9	PLIF25-16	PLIF Convex 0° Cage, Ti 16mm x 25mm

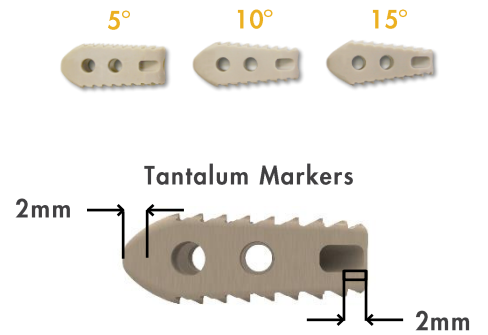
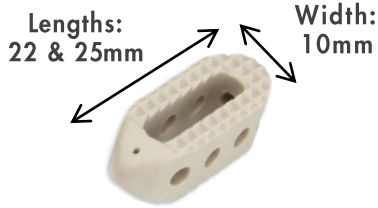
PLIF Convex Sizers (Monolithic)



PLIF Wide Cages 5°, 10° & 15° (PEEK)

Features

- Aggressive Tooth Pattern to Prevent Retropulsion
- Large Graft Window
- Bulleted Nose
- Length: 22 & 25mm
- Height: 8-16mm (1mm increments)
- Width: 10mm
- Lordosis: 5°, 10° & 15°



PLIF Wide Sizers (5° & 10°) Monolithic



PLIF Wide Sizers (15°) Modular



PLIF Wide 15° Paddle Shavers (Modular)



PLIF Wide 15° Paddle Distractors (Modular)



INSTRUMENTS

Inserter



Slap Hammer

(ONLY AVAILABLE WITH THE 15° CAGES)

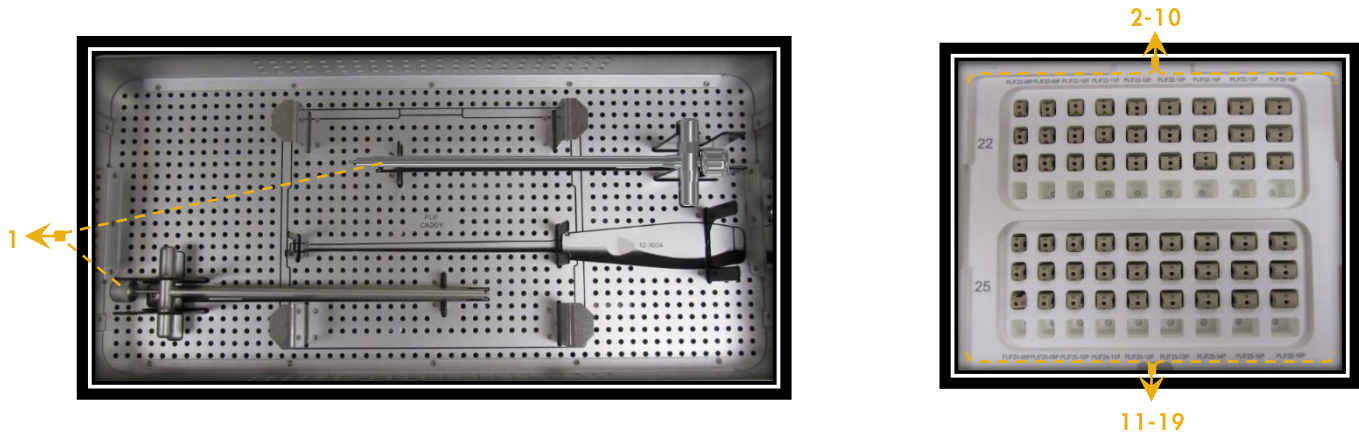


PLIF Convex 0° Sizers – Top Tray (21-1001-CAT)



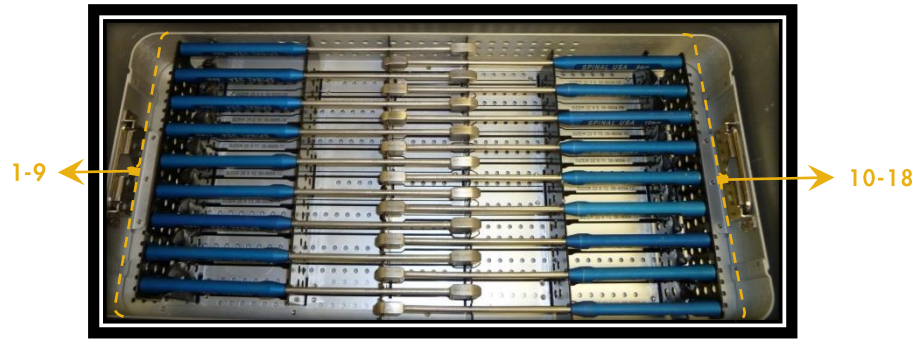
#	Item No.	Description	Qty	#	Item No.	Description	Qty
1	00-9005-08	PLIF Convex 0° Sizer 8mm x 25mm	1	10	00-9004-08	PLIF Convex 0° Sizer 8mm x 22mm	1
2	00-9005-09	PLIF Convex 0° Sizer 9mm x 25mm	1	11	00-9004-09	PLIF Convex 0° Sizer 9mm x 22mm	1
3	00-9005-10	PLIF Convex 0° Sizer 10mm x 25mm	1	12	00-9004-10	PLIF Convex 0° Sizer 10mm x 22mm	1
4	00-9005-11	PLIF Convex 0° Sizer 11mm x 25mm	1	13	00-9004-11	PLIF Convex 0° Sizer 11mm x 22mm	1
5	00-9005-12	PLIF Convex 0° Sizer 12mm x 25mm	1	14	00-9004-12	PLIF Convex 0° Sizer 12mm x 22mm	1
6	00-9005-13	PLIF Convex 0° Sizer 13mm x 25mm	1	15	00-9004-13	PLIF Convex 0° Sizer 13mm x 22mm	1
7	00-9005-14	PLIF Convex 0° Sizer 14mm x 25mm	1	16	00-9004-14	PLIF Convex 0° Sizer 14mm x 22mm	1
8	00-9005-15	PLIF Convex 0° Sizer 15mm x 25mm	1	17	00-9004-15	PLIF Convex 0° Sizer 15mm x 22mm	1
9	00-9005-16	PLIF Convex 0° Sizer 16mm x 25mm	1	18	00-9004-16	PLIF Convex 0° Sizer 16mm x 22mm	1

PLIF Convex Cages - Bottom Tray (21-1001-CAT)



#	Item No.	Description	Qty	#	Item No.	Description	Qty
1	12-9012	PLIF Cage Insertor	1	11	PLIF25-08P	PLIF Convex 0° Cage, Peek 8mm x 25mm	3
2	PLIF22-08P	PLIF Convex 0° Cage, Peek 8mm x 22mm	3	12	PLIF25-09P	PLIF Convex 0° Cage, Peek 9mm x 25mm	3
3	PLIF22-09P	PLIF Convex 0° Cage, Peek 9mm x 22mm	3	13	PLIF25-10P	PLIF Convex 0° Cage, Peek 10mm x 25mm	3
4	PLIF22-10P	PLIF Convex 0° Cage, Peek 10mm x 22mm	3	14	PLIF25-11P	PLIF Convex 0° Cage, Peek 11mm x 25mm	3
5	PLIF22-11P	PLIF Convex 0° Cage, Peek 11mm x 22mm	3	15	PLIF25-12P	PLIF Convex 0° Cage, Peek 12mm x 25mm	3
6	PLIF22-12P	PLIF Convex 0° Cage, Peek 12mm x 22mm	3	16	PLIF25-13P	PLIF Convex 0° Cage, Peek 13mm x 25mm	3
7	PLIF22-13P	PLIF Convex 0° Cage, Peek 13mm x 22mm	3	17	PLIF25-14P	PLIF Convex 0° Cage, Peek 14mm x 25mm	3
8	PLIF22-14P	PLIF Convex 0° Cage, Peek 14mm x 22mm	3	18	PLIF25-15P	PLIF Convex 0° Cage, Peek 15mm x 25mm	3
9	PLIF22-15P	PLIF Convex 0° Cage, Peek 15mm x 22mm	3	19	PLIF25-16P	PLIF Convex 0° Cage, Peek 16mm x 25mm	3
10	PLIF22-16P	PLIF Convex 0° Cage, Peek 16mm x 22mm	3				

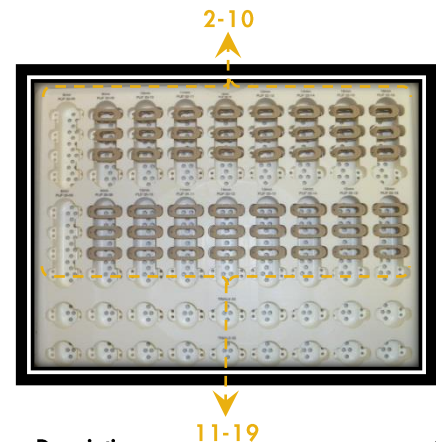
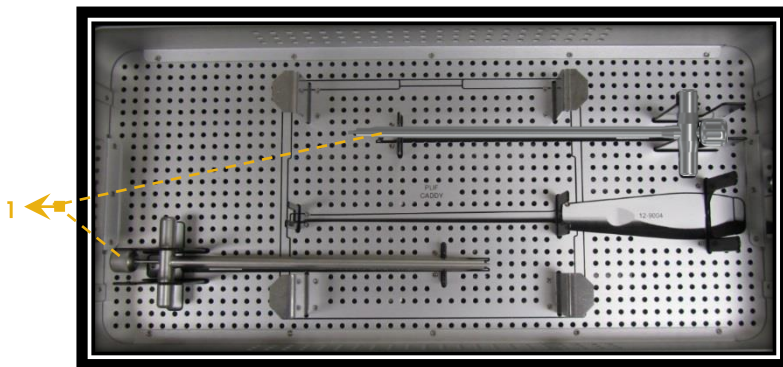
PLIF WIDE 5° Sizers – Top Tray (21-1001-CAT3)



#	Item No.	Description	Qty
1	00-9005-08	PLIF 0° Convex Sizer 8mm x 25mm	1
2	00-9005-09	PLIF 0° Convex Sizer 9mm x 25mm	1
3	00-9005-10	PLIF 0° Convex Sizer 10mm x 25mm	1
4	00-9005-11	PLIF 0° Convex Sizer 11mm x 25mm	1
5	00-9005-12	PLIF 0° Convex Sizer 12mm x 25mm	1
6	00-9005-13	PLIF 0° Convex Sizer 13mm x 25mm	1
7	00-9005-14	PLIF 0° Convex Sizer 14mm x 25mm	1
8	00-9005-15	PLIF 0° Convex Sizer 15mm x 25mm	1
9	00-9005-16	PLIF 0° Convex Sizer 16mm x 25mm	1

#	Item No.	Description	Qty
10	00-9004-08	PLIF 0° Convex Sizer 8mm x 22mm	1
11	00-9004-09	PLIF 0° Convex Sizer 9mm x 22mm	1
12	00-9004-10	PLIF 0° Convex Sizer 10mm x 22mm	1
13	00-9004-11	PLIF 0° Convex Sizer 11mm x 22mm	1
14	00-9004-12	PLIF 0° Convex Sizer 12mm x 22mm	1
15	00-9004-13	PLIF 0° Convex Sizer 13mm x 22mm	1
16	00-9004-14	PLIF 0° Convex Sizer 14mm x 22mm	1
17	00-9004-15	PLIF 0° Convex Sizer 15mm x 22mm	1
18	00-9004-16	PLIF 0° Convex Sizer 16mm x 22mm	1

PLIF WIDE 5° Cages - Bottom Tray (21-1001-CAT3)



#	Item No.	Description	Qty
1	12-9012	PLIF Cage Inserter	1
2	26-221005-08	PLIF Wide 5° Cage, Peek 8mm x 22mm	3
3	26-221005-09	PLIF Wide 5° Cage, Peek 9mm x 22mm	3
4	26-221005-10	PLIF Wide 5° Cage, Peek 10mm x 22mm	3
5	26-221005-11	PLIF Wide 5° Cage, Peek 11mm x 22mm	3
6	26-221005-12	PLIF Wide 5° Cage, Peek 12mm x 22mm	3
7	26-221005-13	PLIF Wide 5° Cage, Peek 13mm x 22mm	3
8	26-221005-14	PLIF Wide 5° Cage, Peek 14mm x 22mm	3
9	26-221005-15	PLIF Wide 5° Cage, Peek 15mm x 22mm	3
10	26-221005-16	PLIF Wide 5° Cage, Peek 16mm x 22mm	3

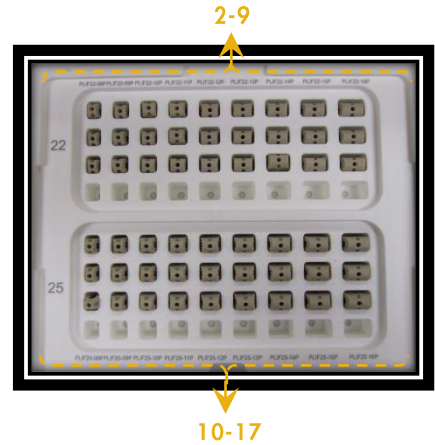
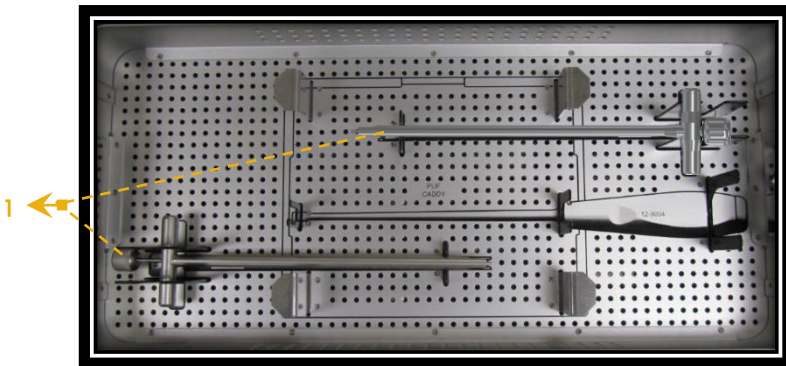
#	Item No.	Description	Qty
11	26-251005-08	PLIF Wide 5° Cage, Peek 8mm x 25mm	3
12	26-251005-09	PLIF Wide 5° Cage, Peek 9mm x 25mm	3
13	26-251005-10	PLIF Wide 5° Cage, Peek 10mm x 25mm	3
14	26-251005-11	PLIF Wide 5° Cage, Peek 11mm x 25mm	3
15	26-251005-12	PLIF Wide 5° Cage, Peek 12mm x 25mm	3
16	26-251005-13	PLIF Wide 5° Cage, Peek 13mm x 25mm	3
17	26-251005-14	PLIF Wide 5° Cage, Peek 14mm x 25mm	3
18	26-251005-15	PLIF Wide 5° Cage, Peek 15mm x 25mm	3
19	26-251005-16	PLIF Wide 5° Cage, Peek 16mm x 25mm	3

PLIF WIDE 10° Sizers – Top Tray (21-1001-CAT2)



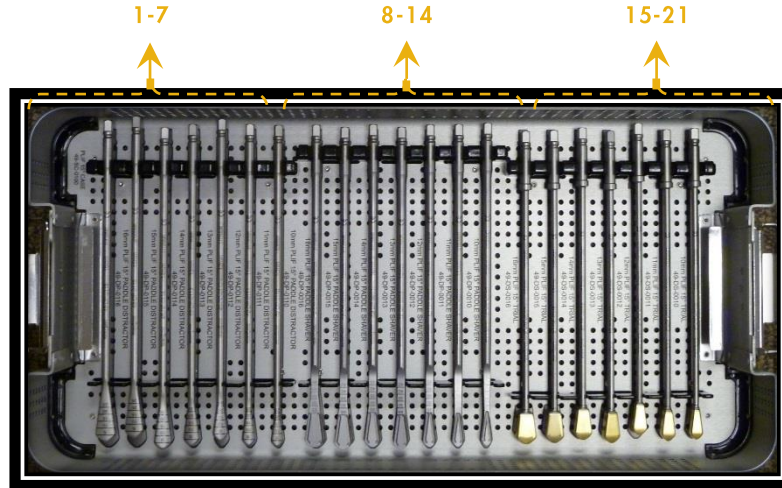
#	Item No.	Description	Qty	#	Item No.	Description	Qty
1	00-9005-08	PLIF 0° Convex Sizer 8mm x 25mm	1	10	00-9004-08	PLIF 0° Convex Sizer 8mm x 22mm	1
2	00-9005-09	PLIF 0° Convex Sizer 9mm x 25mm	1	11	00-9004-09	PLIF 0° Convex Sizer 9mm x 22mm	1
3	00-9005-10	PLIF 0° Convex Sizer 10mm x 25mm	1	12	00-9004-10	PLIF 0° Convex Sizer 10mm x 22mm	1
4	00-9005-11	PLIF 0° Convex Sizer 11mm x 25mm	1	13	00-9004-11	PLIF 0° Convex Sizer 11mm x 22mm	1
5	00-9005-12	PLIF 0° Convex Sizer 12mm x 25mm	1	14	00-9004-12	PLIF 0° Convex Sizer 12mm x 22mm	1
6	00-9005-13	PLIF 0° Convex Sizer 13mm x 25mm	1	15	00-9004-13	PLIF 0° Convex Sizer 13mm x 22mm	1
7	00-9005-14	PLIF 0° Convex Sizer 14mm x 25mm	1	16	00-9004-14	PLIF 0° Convex Sizer 14mm x 22mm	1
8	00-9005-15	PLIF 0° Convex Sizer 15mm x 25mm	1	17	00-9004-15	PLIF 0° Convex Sizer 15mm x 22mm	1
9	00-9005-16	PLIF 0° Convex Sizer 16mm x 25mm	1	18	00-9004-16	PLIF 0° Convex Sizer 16mm x 22mm	1

PLIF WIDE 10° Cages - Bottom Tray (21-1001-CAT2)



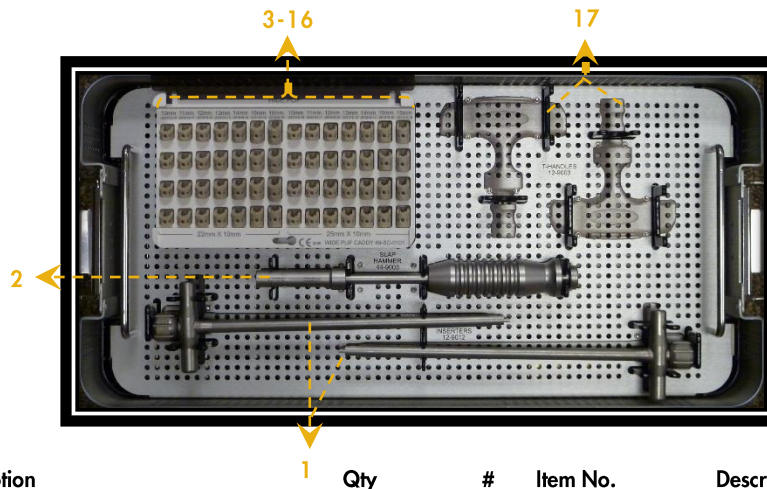
#	Item No.	Description	Qty	#	Item No.	Description	Qty
1	12-9012	PLIF Cage Inserter	1	10	26-251010-09	PLIF Wide 10° Cage, 9mm x 25mm	3
2	26-221010-09	PLIF Wide 10° Cage, 9mm x 22mm	3	11	26-251010-10	PLIF Wide 10° Cage, 10mm x 25mm	3
3	26-221010-10	PLIF Wide 10° Cage, 10mm x 22mm	3	12	26-251010-11	PLIF Wide 10° Cage, 11mm x 25mm	3
4	26-221010-11	PLIF Wide 10° Cage, 11mm x 22mm	3	13	26-251010-12	PLIF Wide 10° Cage, 12mm x 25mm	3
5	26-221010-12	PLIF Wide 10° Cage, 12mm x 22mm	3	14	26-251010-13	PLIF Wide 10° Cage, 13mm x 25mm	3
6	26-221010-13	PLIF Wide 10° Cage, 13mm x 22mm	3	15	26-251010-14	PLIF Wide 10° Cage, 14mm x 25mm	3
7	26-221010-14	PLIF Wide 10° Cage, 14mm x 22mm	3	16	26-251010-15	PLIF Wide 10° Cage, 15mm x 25mm	3
8	26-221010-15	PLIF Wide 10° Cage, 15mm x 22mm	3	17	26-251010-16	PLIF Wide 10° Cage, 16mm x 25mm	3
9	26-221010-16	PLIF Wide 10° Cage, 16mm x 22mm	3				

PLIF WIDE 15° Shavers, Distractors & Sizers – Top Tray (49-BK-0100)



#	Item No.	Description	Qty	#	Item No.	Description	Qty
1	49-DP-0110	PLIF Wide 15° Paddle Distractor; Modular 10mm	1	12	49-DP-0014	PLIF Wide 15° Paddle Shaver; Modular 14mm	1
2	49-DP-0111	PLIF Wide 15° Paddle Distractor; Modular 11mm	1	13	49-DP-0015	PLIF Wide 15° Paddle Shaver; Modular 15mm	1
3	49-DP-0112	PLIF Wide 15° Paddle Distractor; Modular 12mm	1	14	49-DP-0016	PLIF Wide 15° Paddle Shaver; Modular 16mm	1
4	49-DP-0113	PLIF Wide 15° Paddle Distractor; Modular 13mm	1	15	49-DS-0010	PLIF Wide 15° Trial; Modular 10mm	1
5	49-DP-0114	PLIF Wide 15° Paddle Distractor; Modular 14mm	1	16	49-DS-0011	PLIF Wide 15° Trial; Modular 11mm	1
6	49-DP-0115	PLIF Wide 15° Paddle Distractor; Modular 15mm	1	17	49-DS-0012	PLIF Wide 15° Trial; Modular 12mm	1
7	49-DP-0116	PLIF Wide 15° Paddle Distractor; Modular 16mm	1	18	49-DS-0013	PLIF Wide 15° Trial; Modular 13mm	1
8	49-DP-0010	PLIF Wide 15° Paddle Shaver; Modular 10mm	1	19	49-DS-0014	PLIF Wide 15° Trial; Modular 14mm	1
9	49-DP-0011	PLIF Wide 15° Paddle Shaver; Modular 11mm	1	20	49-DS-0015	PLIF Wide 15° Trial; Modular 15mm	1
10	49-DP-0012	PLIF Wide 15° Paddle Shaver; Modular 12mm	1	21	49-DS-0016	PLIF Wide 15° Trial; Modular 16mm	1
11	49-DP-0013	PLIF Wide 15° Paddle Shaver; Modular 13mm	1				

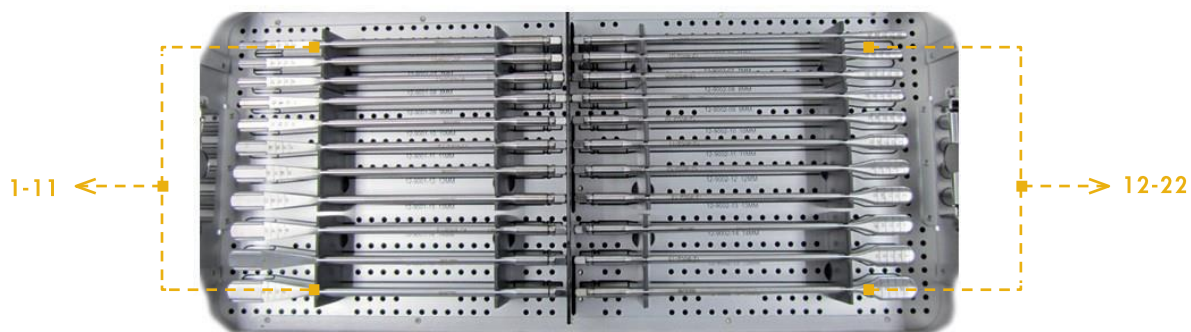
PLIF WIDE 15° Cages - Bottom Tray (49-BK-0100)



#	Item No.	Description	Qty	#	Item No.	Description	Qty
1	12-9012	Insertor; PLIF/TLIF/TPLIF Cages	2	10	26-251015-10	PLIF Wide 15° Cage, Peek 10mm x 25mm	4
2	44-9003	Slap Hammer	1	11	26-251015-11	PLIF Wide 15° Cage, Peek 11mm x 25mm	4
3	26-221015-10	PLIF Wide 15° Cage, Peek 10mm x 22mm	4	12	26-251015-12	PLIF Wide 15° Cage, Peek 12mm x 25mm	4
4	26-221015-11	PLIF Wide 15° Cage, Peek 11mm x 22mm	4	13	26-251015-13	PLIF Wide 15° Cage, Peek 13mm x 25mm	4
5	26-221015-12	PLIF Wide 15° Cage, Peek 12mm x 22mm	4	14	26-251015-14	PLIF Wide 15° Cage, Peek 14mm x 25mm	4
6	26-221015-13	PLIF Wide 15° Cage, Peek 13mm x 22mm	4	15	26-251015-15	PLIF Wide 15° Cage, Peek 15mm x 25mm	4
7	26-221015-14	PLIF Wide 15° Cage, Peek 14mm x 22mm	4	16	26-251015-16	PLIF Wide 15° Cage, Peek 16mm x 25mm	4
8	26-221015-15	PLIF Wide 15° Cage, Peek 15mm x 22mm	4	17	12-9003	T-Handle; Quick Release	2
9	26-221015-16	PLIF Wide 15° Cage, Peek 16mm x 22mm	4				

PLIF / TLIF / T-PLIF Instrument Tray 1 – Top Tray (21-1007-CAT)

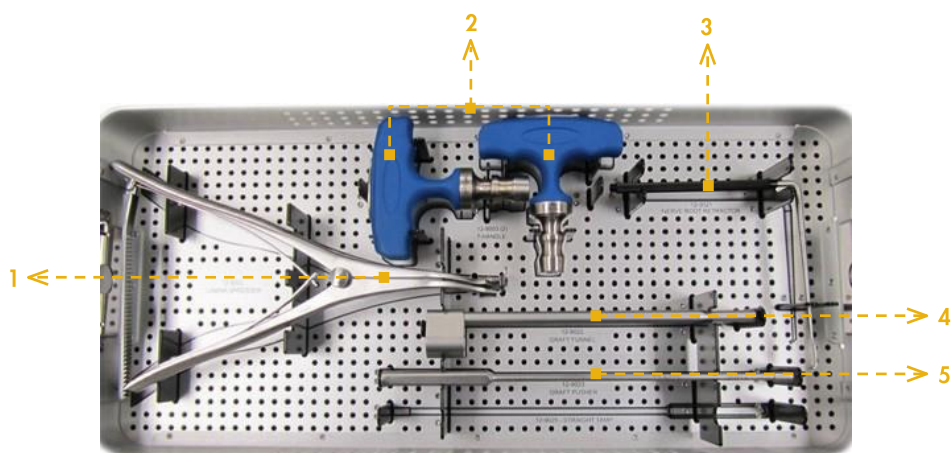
BY REQUEST ONLY



#	Item No.	Description	Qty	#	Item No.	Description	Qty
1	12-9001-06	PLIF Convex 0° Paddle Shaver; Modular 6mm	1	12	12-9002-06	PLIF Convex 0° Paddle Distractor; Modular 6mm	1
2	12-9001-07	PLIF Convex 0° Paddle Shaver; Modular 7mm	1	13	12-9002-07	PLIF Convex 0° Paddle Distractor; Modular 7mm	1
3	12-9001-08	PLIF Convex 0° Paddle Shaver; Modular 8mm	1	14	12-9002-08	PLIF Convex 0° Paddle Distractor; Modular 8mm	1
4	12-9001-09	PLIF Convex 0° Paddle Shaver; Modular 9mm	1	15	12-9002-09	PLIF Convex 0° Paddle Distractor; Modular 9mm	1
5	12-9001-10	PLIF Convex 0° Paddle Shaver; Modular 10mm	1	16	12-9002-10	PLIF Convex 0° Paddle Distractor; Modular 10mm	1
6	12-9001-11	PLIF Convex 0° Paddle Shaver; Modular 11mm	1	17	12-9002-11	PLIF Convex 0° Paddle Distractor; Modular 11mm	1
7	12-9001-12	PLIF Convex 0° Paddle Shaver; Modular 12mm	1	18	12-9002-12	PLIF Convex 0° Paddle Distractor; Modular 12mm	1
8	12-9001-13	PLIF Convex 0° Paddle Shaver; Modular 13mm	1	19	12-9002-13	PLIF Convex 0° Paddle Distractor; Modular 13mm	1
9	12-9001-14	PLIF Convex 0° Paddle Shaver; Modular 14mm	1	20	12-9002-14	PLIF Convex 0° Paddle Distractor; Modular 14mm	1
10	12-9001-15	PLIF Convex 0° Paddle Shaver; Modular 15mm	1	21	12-9002-15	PLIF Convex 0° Paddle Distractor; Modular 15mm	1
11	12-9001-16	PLIF Convex 0° Paddle Shaver; Modular 16mm	1	22	12-9002-16	PLIF Convex 0° Paddle Distractor; Modular 16mm	1

PLIF / TLIF / T-PLIF Instrument Tray 1 – Bottom Tray (21-1007-CAT)

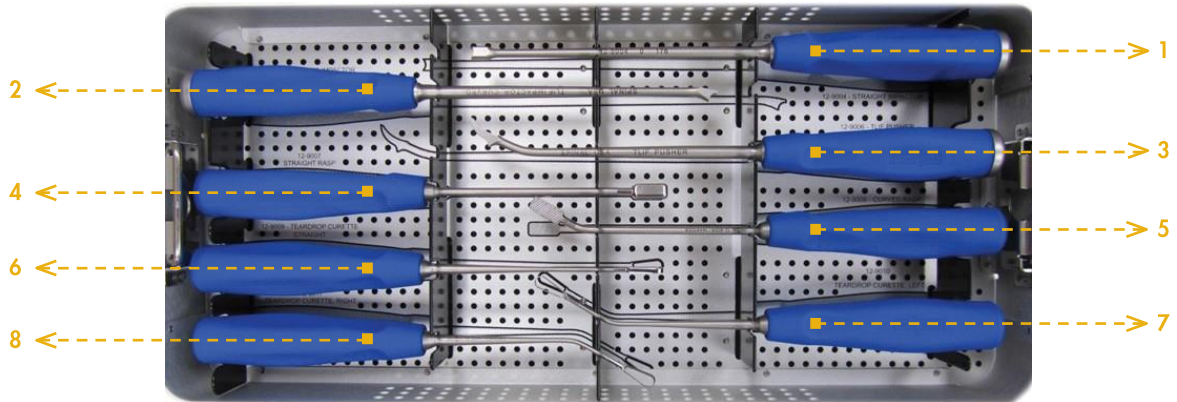
BY REQUEST ONLY



#	Item No.	Description	Qty	#	Item No.	Description	Qty
1	12-9020	Lamina Spreader	1	4	12-9026	Graft Funnel	1
2	12-9003	T-Handle Quick release	2	5	12-9023	Graft Pusher	1
3	12-9021	Scoville Nerve Root Retractor 90 degree	1				

PLIF / TLIF / T-PLIF Instrument Tray 2 – Top Tray (21-1008-CAT)

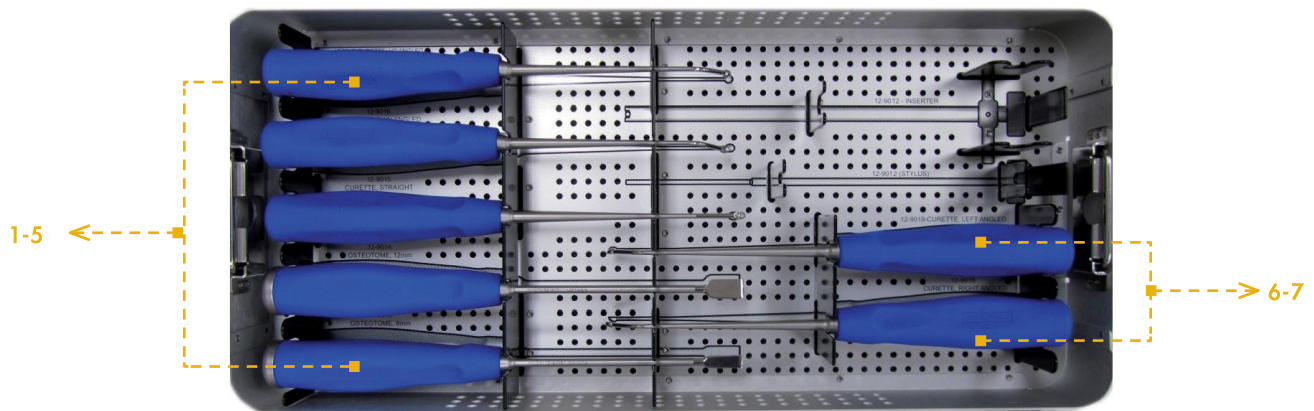
BY REQUEST ONLY



#	Item No.	Description	Qty	#	Item No.	Description	Qty
1	12-9004	TLIF Impactor, Straight	1	5	12-9008	Rasp, Curved	1
2	12-9005	TLIF Impactor, Curved	1	6	12-9009	Curette, Teardrop, Straight 8mm	1
3	12-9006	TLIF Pusher	1	7	12-9010	Curette, Teardrop, Right Angle 8mm	1
4	12-9007	Rasp, Straight	1	8	12-9011	Curette, Teardrop, Left Angle 8mm	1

PLIF / TLIF / T-PLIF Instrument Tray 2 – Bottom Tray (21-1008-CAT)

BY REQUEST ONLY



#	Item No.	Description	Qty	#	Item No.	Description	Qty
1	12-9017	Curette, Up Angled	1	6	12-9018	Curette, Left Angled	1
2	12-9016	Curette, Down Angled	1	7	12-9019	Curette, Right Angled	1
3	12-9015	Curette, Straight	1				
4	12-9014	Osteotome, 12mm	1				
5	12-9013	Osteotome, 8mm	1				

SURGICAL TECHNIQUE

1

PATIENT POSITIONING

The patient should be placed prone, in the appropriate position for a posterior approach, and shall be draped in a manner consistent with surgical facility protocol. Utilizing Anterior and Posterior fluoroscopic imaging and palpation of the patient anatomy, the affected level is identified and marked appropriately for incisions.

2

ENDPLATE PREPARATION

Upon proper targeting of the affected level(s) a skin incision is made. The soft tissues are dissected and retracted providing the desired visualization of the bony anatomy. The lateral inferior portion of the inferior facet of the superior vertebrae is removed with an osteotome, burr or Kerrison.

The capsular portion of the ligamentum flavum is exposed and resected. The superior facet of the inferior vertebrae is resected with an osteotome, burr or Kerrison.

The neural foramen and central spine canal are decompressed as necessary. The posterolateral portion of the annular fibrosis is exposed and an annular window is created to gain access to the intervertebral space.

Additional distraction can be gained with the use of the Paddle Distractors. A discectomy is then performed. The superficial layers of the cartilaginous endplates are removed utilizing Paddle Shavers.

SURGICAL TECHNIQUE

3

IMPLANT SELECTION

At the surgeon's discretion, posterior distraction of the vertebral space may be performed. Attach the appropriate Sizer into the annulotomy window and position within the intervertebral space (Fig. 1). Confirm positioning with A/P and lateral fluoroscopy.

Repeat the trial process until the desired amount of distraction is achieved within the intervertebral space. The height and length of the implant are determined from the final Sizer.

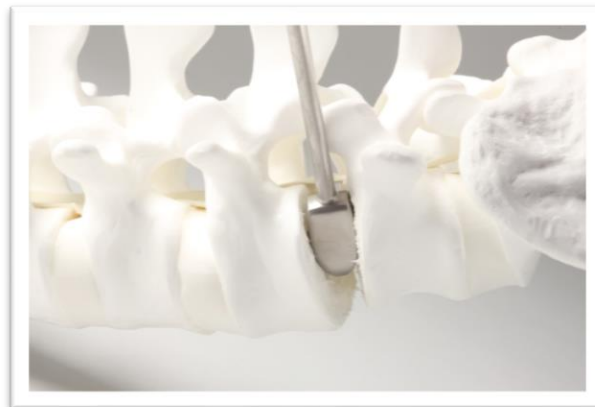


Figure 1

4

IMPLANT INSERTION

Place the appropriate size implant onto the Inserter (12-9012) and tighten (Fig. 2). The implant has a large graft window to accept Bone Graft Material (Fig. 3).

Insert the implant into the disc space with the final implant height dimension oriented in the plane of the disc (Fig. 4). Remove the Inserter from the Implant by turning the threaded knob counterclockwise until it is free from the implant. Repeat the implant insertion process for the implant on the contralateral side.



Figure 2



Figure 3

5

CLOSURE/IMPLANT REMOVAL

Closure

After visual and radiographic confirmation of the implant placement, the closure process can proceed. This surgical technique is a general guide. The surgeon should be familiar with Posterior Lumbar Interbody Fusion.

Implant Removal

If needed, the implant can be removed using the PLIF Inserter (12-9012).



Figure 4

INDICATIONS

CONTRAINDICATIONS:

The ShurFit® Interbody Fusion Devices contraindications include, but not limited to:

1. Prior fusion at the level(s) to be treated
2. Any condition not described in the indications for use
3. Previous vascular approach
4. Iliofemoral arteriosclerosis
5. Morbid obesity
6. Mental illness
7. Pregnancy
8. Local infection or inflammation
9. Any case needing to mix metals from different components
10. Any patient unwilling to cooperate with postoperative instructions
11. All cases not stated in the indications
12. Reuse, or multiple uses

POTENTIAL ADVERSE AFFECTS:

The following potential adverse affects associated with the procedure have been shown to occur with the use of similar spinal systems. All patients considered candidates for fusion should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse affects. The following are potential adverse affects, but not limited to:

1. Loss of proper spinal curvature, correction, height, and/or reduction
2. Infection
3. Non-Union or delayed union
4. Foreign body reaction to the implants
5. Hemorrhaging
6. Loss of neurological function, dural tear, pain, and/or discomfort
7. Autograft fracture, vertebral body fracture or discontinued growth of fused at, above and/or below the surgery level
8. Bending, loosening, fracture, disassembly, slippage and/or migration of the components
9. Pain or discomfort
10. Change in mental status
11. Bursitis
12. Bone loss and/or bone fracture due to stress shielding
13. Inability to resume activities of normal daily activities
14. Revision surgery
15. Death

WARNINGS:

The following are warnings for this device.

1. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without previous surgery.
2. Potential risks identified with the use of this device system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, necrosis of the bone, neurological injury, and/or vascular or visceral injury.
3. The benefit of spinal fusions utilizing any interbody fusion device has not been adequately established in patients with stable spines.
4. Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Patients who smoke or abuse alcohol are poor candidates for spinal fusion.
5. Patients who smoke should be advised of the consequences of the fact that an increased incidence of non-union has been reported with patients who smoke.
6. The implants and instruments are provided non-sterile and must be cleaned and sterilized before use. Device components should be sterilized using one of the noted validated sterilization cycle parameters.
7. A successful result is not always achieved in every surgical case due to many extenuating circumstances. This is especially true in spinal surgeries where other patient conditions may compromise the results.
8. Never reuse an internal fixation device under any circumstances.
9. This device is not intended to be the sole means of spinal support. The ShurFit Interbody Fusion Devices must be used with additional anterior and/or posterior instrumentation to augment stability.
10. Only surgeons trained and experienced in spinal decompression and autografting techniques should use the ShurFit Interbody Fusion Devices. Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants are essential considerations in the utilization of this device.
11. Physician note: Although the physician is the learned intermediary, the important medical information given in this document should be conveyed to the patient.
12. Do not reuse implants. Discard used, damaged, or otherwise suspect implants. **AN IMPLANT SHOULD NEVER BE RE-USED.** Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure. Reuse can potentially compromise device performance and patient safety.



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