

PRECISION SPINE
SHURFIT™
PLIF INTERBODY CAGES

Surgical Technique

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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 medical grade polyetheretherketone (Using PEEK-OPTIMA® polymer from INVIBIO®). The products are supplied clean and "NON-STERILE".

Product Highlights:

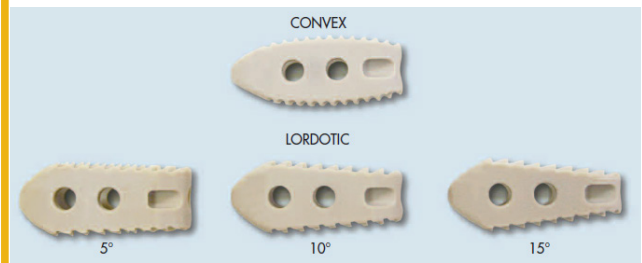
- Large graft area provides generous biological coverage
- Convex and Lordotic (Available in 5°, 10° & 15°) Series
- Bulleted nose helps facilitate insertion

Indications:

The ShurFit Posterior Lumbar Interbody Fusion System (PLIF) is indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. Two devices are used per intervertebral space for the PLIF system.

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.



IMPLANT SPECIFICATIONS

ShurFit™ Wide PLIF

- Length: 22 & 25mm
- Height: 8-16mm (1mm increments)
- Width: 10mm
- Lordosis: 5 degree, 10 degree & 15 degree

ShurFit™ Convex PLIF

- Length: 22 & 25mm
- Height: 8-16mm (1mm increments)
- Width: 9mm



22mm Wide Lordotic PLIF Cages

Part Number 5 Degree

26-221005-08	Wide PLIF Cage PEEK 5 deg 8 x 22mm
26-221005-09	Wide PLIF Cage PEEK 5 deg 9 x 22mm
26-221005-10	Wide PLIF Cage PEEK 5 deg 10 x 22mm
26-221005-11	Wide PLIF Cage PEEK 5 deg 11 x 22mm
26-221005-12	Wide PLIF Cage PEEK 5 deg 12 x 22mm
26-221005-13	Wide PLIF Cage PEEK 5 deg 13 x 22mm
26-221005-14	Wide PLIF Cage PEEK 5 deg 14 x 22mm
26-221005-15	Wide PLIF Cage PEEK 5 deg 15 x 22mm
26-221005-16	Wide PLIF Cage PEEK 5 deg 16 x 22mm

Part Number 10 Degree

26-221010-09	Wide PLIF Cage PEEK 10 deg 9 x 22mm
26-221010-10	Wide PLIF Cage PEEK 10 deg 10 x 22mm
26-221010-11	Wide PLIF Cage PEEK 10 deg 11 x 22mm
26-221010-12	Wide PLIF Cage PEEK 10 deg 12 x 22mm
26-221010-13	Wide PLIF Cage PEEK 10 deg 13 x 22mm
26-221010-14	Wide PLIF Cage PEEK 10 deg 14 x 22mm
26-221010-15	Wide PLIF Cage PEEK 10 deg 15 x 22mm
26-221010-16	Wide PLIF Cage PEEK 10 deg 16 x 22mm

Part Number 15 Degree

26-221015-10	Wide PLIF Cage PEEK 15 deg 10 x 22mm
26-221015-11	Wide PLIF Cage PEEK 15 deg 11 x 22mm
26-221015-12	Wide PLIF Cage PEEK 15 deg 12 x 22mm
26-221015-13	Wide PLIF Cage PEEK 15 deg 13 x 22mm
26-221015-14	Wide PLIF Cage PEEK 15 deg 14 x 22mm
26-221015-15	Wide PLIF Cage PEEK 15 deg 15 x 22mm
26-221015-16	Wide PLIF Cage PEEK 15 deg 16 x 22mm



25mm Wide Lordotic PLIF Cages

Part Number	5 Degree	Part Number	10 Degree
26-251005-08	Wide PLIF Cage PEEK 5 deg 8 x 25mm	26-251010-09	Wide PLIF Cage PEEK 10 deg 9 x 25mm
26-251005-09	Wide PLIF Cage PEEK 5 deg 9 x 25mm	26-251010-10	Wide PLIF Cage PEEK 10 deg 10 x 25mm
26-251005-10	Wide PLIF Cage PEEK 5 deg 10 x 25mm	26-251010-11	Wide PLIF Cage PEEK 10 deg 11 x 25mm
26-251005-11	Wide PLIF Cage PEEK 5 deg 11 x 25mm	26-251010-12	Wide PLIF Cage PEEK 10 deg 12 x 25mm
26-251005-12	Wide PLIF Cage PEEK 5 deg 12 x 25mm	26-251010-13	Wide PLIF Cage PEEK 10 deg 13 x 25mm
26-251005-13	Wide PLIF Cage PEEK 5 deg 13 x 25mm	26-251010-14	Wide PLIF Cage PEEK 10 deg 14 x 25mm
26-251005-14	Wide PLIF Cage PEEK 5 deg 14 x 25mm	26-251010-15	Wide PLIF Cage PEEK 10 deg 15 x 25mm
26-251005-15	Wide PLIF Cage PEEK 5 deg 15 x 25mm	26-251010-16	Wide PLIF Cage PEEK 10 deg 16 x 25mm
26-251005-16	Wide PLIF Cage PEEK 5 deg 16 x 25mm		

Part Number	15 Degree
26-251015-10	Wide PLIF Cage PEEK 15 deg 10 x 25mm
26-251015-11	Wide PLIF Cage PEEK 15 deg 11 x 25mm
26-251015-12	Wide PLIF Cage PEEK 15 deg 12 x 25mm
26-251015-13	Wide PLIF Cage PEEK 15 deg 13 x 25mm
26-251015-14	Wide PLIF Cage PEEK 15 deg 14 x 25mm
26-251015-15	Wide PLIF Cage PEEK 15 deg 15 x 25mm
26-251015-16	Wide PLIF Cage PEEK 15 deg 16 x 25mm



PLIF Convex Sizes

Part Number	22mm	Part Number	25mm
PLIF22-08P	PLIF Cage PEEK 8 x 22mm	PLIF25-08P	PLIF Cage PEEK 8 x 25mm
PLIF22-09P	PLIF Cage PEEK 9 x 22mm	PLIF25-09P	PLIF Cage PEEK 9 x 25mm
PLIF22-10P	PLIF Cage PEEK 10 x 22mm	PLIF25-10P	PLIF Cage PEEK 10 x 25mm
PLIF22-11P	PLIF Cage PEEK 11 x 22mm	PLIF25-11P	PLIF Cage PEEK 11 x 25mm
PLIF22-12P	PLIF Cage PEEK 12 x 22mm	PLIF25-12P	PLIF Cage PEEK 12 x 25mm
PLIF22-13P	PLIF Cage PEEK 13 x 22mm	PLIF25-13P	PLIF Cage PEEK 13 x 25mm
PLIF22-14P	PLIF Cage PEEK 14 x 22mm	PLIF25-14P	PLIF Cage PEEK 14 x 25mm
PLIF22-15P	PLIF Cage PEEK 15 x 22mm	PLIF25-15P	PLIF Cage PEEK 15 x 25mm
PLIF22-16P	PLIF Cage PEEK 16 x 22mm	PLIF25-16P	PLIF Cage PEEK 16 x 25mm

INSTRUMENT SPECIFICATIONS

PLIF Sizers

Part Number	22mm Sizers (Monolithic)
00-9004-08	PLIF Sizer 8 x 22mm
00-9004-09	PLIF Sizer 9 x 22mm
00-9004-10	PLIF Sizer 10 x 22mm
00-9004-11	PLIF Sizer 11 x 22mm
00-9004-12	PLIF Sizer 12 x 22mm
00-9004-13	PLIF Sizer 13 x 22mm
00-9004-14	PLIF Sizer 14 x 22mm
00-9004-15	PLIF Sizer 15 x 22mm
00-9004-16	PLIF Sizer 16 x 22mm
Part Number	25mm Sizers (Monolithic)
00-9005-08	PLIF Sizer 8 x 25mm
00-9005-09	PLIF Sizer 9 x 25mm
00-9005-11	PLIF Sizer 11 x 25mm
00-9005-12	PLIF Sizer 12 x 25mm
00-9005-13	PLIF Sizer 13 x 25mm
00-9005-14	PLIF Sizer 14 x 25mm
00-9005-15	PLIF Sizer 15 x 25mm
00-9005-16	PLIF Sizer 16 x 25mm
Part Number	15 Degree Sizers (Modular)
49-DS-0010	10mm PLIF 15 Degree Sizer
49-DS-0011	11mm PLIF 15 Degree Sizer
49-DS-0012	12mm PLIF 15 Degree Sizer
49-DS-0013	13mm PLIF 15 Degree Sizer
49-DS-0014	14mm PLIF 15 Degree Sizer
49-DS-0015	15mm PLIF 15 Degree Sizer
49-DS-0016	16mm PLIF 15 Degree Sizer



Paddle Shavers & Distractors

Part Number	15 Degree Paddle Shavers & Distractors
49-DP-0010	10mm PLIF 15 Degree Paddle Shaver
49-DP-0011	11mm PLIF 15 Degree Paddle Shaver
49-DP-0012	12mm PLIF 15 Degree Paddle Shaver
49-DP-0013	13mm PLIF 15 Degree Paddle Shaver
49-DP-0014	14mm PLIF 15 Degree Paddle Shaver
49-DP-0015	15mm PLIF 15 Degree Paddle Shaver
49-DP-0016	16mm PLIF 15 Degree Paddle Shaver
49-DP-0110	11mm PLIF 15 Degree Paddle Distractor
49-DP-0111	11mm PLIF 15 Degree Paddle Distractor
49-DP-0112	12mm PLIF 15 Degree Paddle Distractor
49-DP-0113	13mm PLIF 15 Degree Paddle Distractor
49-DP-0114	14mm PLIF 15 Degree Paddle Distractor
49-DP-0115	15mm PLIF 15 Degree Paddle Distractor
49-DP-0116	16mm PLIF 15 Degree Paddle Distractor
Part Number	0 Degree Paddle Shavers & Distractors
12-9001-06	6mm PLIF 0 Degree Paddle Shaver
12-9001-07	7mm PLIF 0 Degree Paddle Shaver
12-9001-08	8mm PLIF 0 Degree Paddle Shaver
12-9001-09	9mm PLIF 0 Degree Paddle Shaver
12-9001-10	10mm PLIF 0 Degree Paddle Shaver
12-9001-11	11mm PLIF 0 Degree Paddle Shaver
12-9001-12	12mm PLIF 0 Degree Paddle Shaver
12-9001-13	13mm PLIF 0 Degree Paddle Shaver
12-9001-14	14mm PLIF 0 Degree Paddle Shaver
12-9001-15	15mm PLIF 0 Degree Paddle Shaver
12-9001-16	16mm PLIF 0 Degree Paddle Shaver
12-9002-06	6mm PLIF 0 Degree Paddle Distractor
12-9002-07	7mm PLIF 0 Degree Paddle Distractor
12-9002-08	8mm PLIF 0 Degree Paddle Distractor
12-9002-09	9mm PLIF 0 Degree Paddle Distractor
12-9002-10	10mm PLIF 0 Degree Paddle Distractor
12-9002-11	11mm PLIF 0 Degree Paddle Distractor
12-9002-12	12mm PLIF 0 Degree Paddle Distractor
12-9002-13	13mm PLIF 0 Degree Paddle Distractor
12-9002-14	14mm PLIF 0 Degree Paddle Distractor
12-9002-15	15mm PLIF 0 Degree Paddle Distractor
12-9002-16	16mm PLIF 0 Degree Paddle Distractor

Instruments

Part Number	Instruments
12-9012	Insertor
12-9004	Straight Impactor
12-9003	T-Handle
44-9003	Slap Hammer



Insertor



Straight Impactor

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.

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.

A Slap Hammer (44-9003) may be used to assist in positioning the 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 counter-clockwise until it is free from the implant. Final positioning of the implant can be achieved using the Straight Impactor (12-9004). Repeat the implant insertion process for the implant on the contralateral side.

5. Closure/Implant Removal:

Closure

After visual and radiographic confirmation of the implant placement, the closure process can proceed.

The ShurFit™ PLIF System surgical technique is a general guide. The surgeon should be familiar with Posterior Lateral Interbody Fusion.

Implant Removal

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



Figure 2



Figure 3



Figure 4

SHURFIT™ PLIF IMPLANTS & INSTRUMENTS

Implants

Item No.	Description
26-221005-08	Wide PLIF Cage PEEK 5 deg 8 x 22mm
26-221005-09	Wide PLIF Cage PEEK 5 deg 9 x 22mm
26-221005-10	Wide PLIF Cage PEEK 5 deg 10 x 22mm
26-221005-11	Wide PLIF Cage PEEK 5 deg 11 x 22mm
26-221005-12	Wide PLIF Cage PEEK 5 deg 12 x 22mm
26-221005-13	Wide PLIF Cage PEEK 5 deg 13 x 22mm
26-221005-14	Wide PLIF Cage PEEK 5 deg 14 x 22mm
26-221005-15	Wide PLIF Cage PEEK 5 deg 15 x 22mm
26-221005-16	Wide PLIF Cage PEEK 5 deg 16 x 22mm
26-221010-09	Wide PLIF Cage PEEK 10 deg 9 x 22mm
26-221010-10	Wide PLIF Cage PEEK 10 deg 10 x 22mm
26-221010-11	Wide PLIF Cage PEEK 10 deg 11 x 22mm
26-221010-12	Wide PLIF Cage PEEK 10 deg 12 x 22mm
26-221010-13	Wide PLIF Cage PEEK 10 deg 13 x 22mm
26-221010-14	Wide PLIF Cage PEEK 10 deg 14 x 22mm
26-221010-15	Wide PLIF Cage PEEK 10 deg 15 x 22mm
26-221010-16	Wide PLIF Cage PEEK 10 deg 16 x 22mm
26-221015-10	Wide PLIF Cage PEEK 15 deg 10 x 22mm
26-221015-11	Wide PLIF Cage PEEK 15 deg 11 x 22mm
26-221015-12	Wide PLIF Cage PEEK 15 deg 12 x 22mm
26-221015-13	Wide PLIF Cage PEEK 15 deg 13 x 22mm
26-221015-14	Wide PLIF Cage PEEK 15 deg 14 x 22mm
26-221015-15	Wide PLIF Cage PEEK 15 deg 15 x 22mm
26-221015-16	Wide PLIF Cage PEEK 15 deg 16 x 22mm
PLIF22-08P	Convex PLIF Cage PEEK 8 x 22mm
PLIF22-09P	Convex PLIF Cage PEEK 9 x 22mm
PLIF22-10P	Convex PLIF Cage PEEK 10 x 22mm
PLIF22-11P	Convex PLIF Cage PEEK 11 x 22mm
PLIF22-12P	Convex PLIF Cage PEEK 12 x 22mm
PLIF22-13P	Convex PLIF Cage PEEK 13 x 22mm
PLIF22-14P	Convex PLIF Cage PEEK 14 x 22mm
PLIF22-15P	Convex PLIF Cage PEEK 15 x 22mm
PLIF22-16P	Convex PLIF Cage PEEK 16 x 22mm
PLIF25-08P	Convex PLIF Cage PEEK 8 x 25mm
PLIF25-09P	Convex PLIF Cage PEEK 9 x 25mm
PLIF25-10P	Convex PLIF Cage PEEK 10 x 25mm
PLIF25-11P	Convex PLIF Cage PEEK 11 x 25mm
PLIF25-12P	Convex PLIF Cage PEEK 12 x 25mm
PLIF25-13P	Convex PLIF Cage PEEK 13 x 25mm
PLIF25-14P	Convex PLIF Cage PEEK 14 x 25mm
PLIF25-15P	Convex PLIF Cage PEEK 15 x 25mm
PLIF25-16P	Convex PLIF Cage PEEK 16 x 25mm

Instruments

Item No.	Description
00-9004-08	PLIF Sizer 8mm x 22mm
00-9004-09	PLIF Sizer 9mm x 22mm
00-9004-10	PLIF Sizer 10mm x 22mm
00-9004-11	PLIF Sizer 11mm x 22mm
00-9004-12	PLIF Sizer 12mm x 22mm
00-9004-13	PLIF Sizer 13mm x 22mm
00-9004-14	PLIF Sizer 14mm x 22mm
00-9004-15	PLIF Sizer 15mm x 22mm
00-9004-16	PLIF Sizer 16mm x 22mm
00-9005-08	PLIF Sizer 8mm x 25mm
00-9005-09	PLIF Sizer 9mm x 25mm

Instruments

Item No.	Description
00-9005-10	PLIF Sizer 10mm x 25mm
00-9005-11	PLIF Sizer 11mm x 25mm
00-9005-12	PLIF Sizer 12mm x 25mm
00-9005-13	PLIF Sizer 13mm x 25mm
00-9005-14	PLIF Sizer 14mm x 25mm
00-9005-15	PLIF Sizer 15mm x 25mm
00-9005-16	PLIF Sizer 16mm x 25mm
49-DS-0010	10mm PLIF 15 Degree Sizer
49-DS-0011	11mm PLIF 15 Degree Sizer
49-DS-0012	12mm PLIF 15 Degree Sizer
49-DS-0013	13mm PLIF 15 Degree Sizer
49-DS-0014	14mm PLIF 15 Degree Sizer
49-DS-0015	15mm PLIF 15 Degree Sizer
49-DS-0016	16mm PLIF 15 Degree Sizer
49-DP-0010	10mm PLIF 15 Paddle Shaver
49-DP-0011	11mm PLIF 15 Paddle Shaver
49-DP-0012	12mm PLIF 15 Paddle Shaver
49-DP-0013	13mm PLIF 15 Paddle Shaver
49-DP-0014	14mm PLIF 15 Paddle Shaver
49-DP-0015	15mm PLIF 15 Paddle Shaver
49-DP-0016	16mm PLIF 15 Paddle Shaver
49-DP-0110	10mm PLIF 15 Paddle Distractor
49-DP-0111	11mm PLIF 15 Paddle Distractor
49-DP-0112	12mm PLIF 15 Paddle Distractor
49-DP-0113	13mm PLIF 15 Paddle Distractor
49-DP-0114	14mm PLIF 15 Paddle Distractor
49-DP-0115	15mm PLIF 15 Paddle Distractor
49-DP-0116	16mm PLIF 15 Paddle Distractor
12-9003	T-Handle
12-9004	Straight Impactor
12-9012	Insertor
44-9003	Slap Hammer
12-9001-06	6mm PLIF 0 Degree Paddle Shaver
12-9001-07	7mm PLIF 0 Degree Paddle Shaver
12-9001-08	8mm PLIF 0 Degree Paddle Shaver
12-9001-09	9mm PLIF 0 Degree Paddle Shaver
12-9001-10	10mm PLIF 0 Degree Paddle Shaver
12-9001-11	11mm PLIF 0 Degree Paddle Shaver
12-9001-12	12mm PLIF 0 Degree Paddle Shaver
12-9001-13	13mm PLIF 0 Degree Paddle Shaver
12-9001-14	14mm PLIF 0 Degree Paddle Shaver
12-9001-15	15mm PLIF 0 Degree Paddle Shaver
12-9001-16	16mm PLIF 0 Degree Paddle Shaver
12-9002-06	6mm PLIF 0 Degree Paddle Distractor
12-9002-07	7mm PLIF 0 Degree Paddle Distractor
12-9002-08	8mm PLIF 0 Degree Paddle Distractor
12-9002-09	9mm PLIF 0 Degree Paddle Distractor
12-9002-10	10mm PLIF 0 Degree Paddle Distractor
12-9002-11	11mm PLIF 0 Degree Paddle Distractor
12-9002-12	12mm PLIF 0 Degree Paddle Distractor
12-9002-13	13mm PLIF 0 Degree Paddle Distractor
12-9002-14	14mm PLIF 0 Degree Paddle Distractor
12-9002-15	15mm PLIF 0 Degree Paddle Distractor
12-9002-16	16mm PLIF 0 Degree Paddle Distractor

CONTRAINDICATIONS:

The ShurFit™ Posterior Interbody Fusion System (PLIF) contraindications include, but are 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 EFFECTS:

The following potential adverse effects 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 effects.

The following are potential adverse effects, 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. Bone graft 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™ Posterior Lumbar Interbody System (PLIF) must be used with additional anterior and/or posterior instrumentation to augment stability.
10. Only surgeons trained and experienced in spinal decompression and bone grafting techniques should use the ShurFit Posterior Lumbar Interbody System (PLIF). 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 REUSED.** 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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