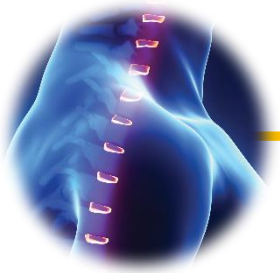


SURGICAL TECHNIQUE

PRECISION SPINE

SHURFIT® 2C

HA–CPTI COATED INTERBODY CAGES

PRECISION SPINE®

Discover the Difference

Made in the USA

TABLE OF CONTENTS

ShurFit® *2C* HA-CPTi Coated Interbody Cages

ShurFit® *2C* OVERVIEW

The ShurFit TLIF *2C*, PLIF *2C*, LLIF *2C* and TPLIF *2C* Interbody Fusion Devices consist 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 (PEEK) and coated with Commercially Pure Titanium and Hydroxyapatite. All implants are supplied clean and "STERILE".

PRODUCT HIGHLIGHTS

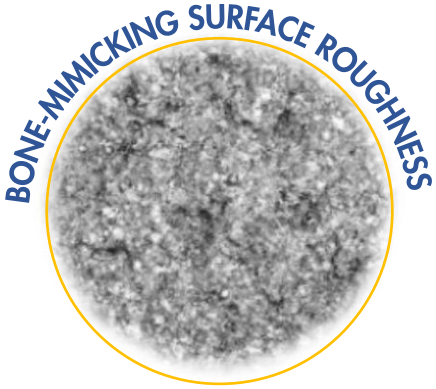
- Biocompatible plasma-sprayed CP Titanium coating with an outer layer of osteoconductive HA
- Aggressive Tooth Pattern to prevent Retropulsion
- Large Graft Window for Maximum Bone Graft Material
- Tantalum Markers for Increased Visualization via fluoroscopy
- Bulleted Nose for Ease of Insertion

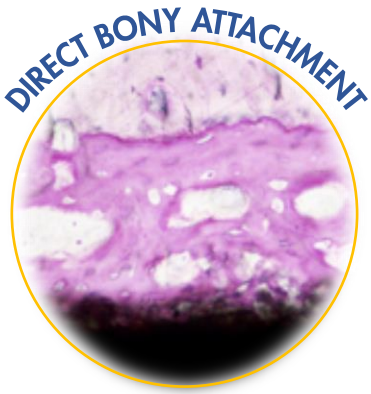
INDICATIONS

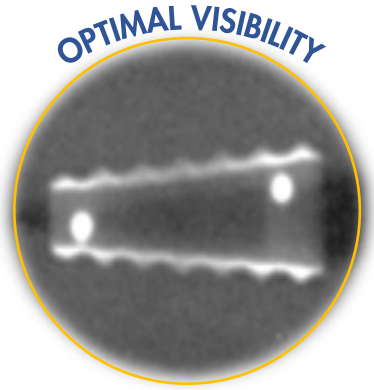
The ShurFit TLIF *2C*, PLIF *2C*, LLIF *2C* and TPLIF *2C* Interbody Fusion Devices are indicated for intervertebral body fusion of the spine in skeletally mature patients. The device system is designed for use with autograft to facilitate fusion. One device is used per intervertebral space for the LLIF *2C*, TLIF *2C* and TPLIF *2C* system. Two devices are used per intervertebral space for the PLIF *2C* system.

The ShurFit TLIF *2C*, PLIF *2C*, LLIF *2C* and TPLIF *2C* Interbody Fusion Devices 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.

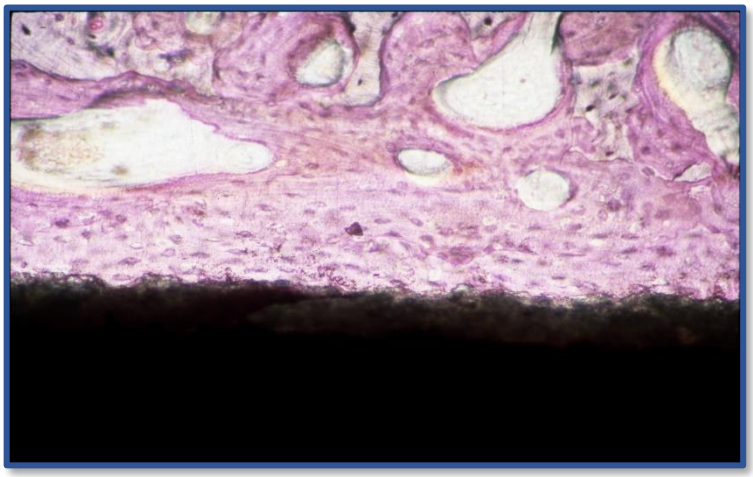
Please refer to package insert (LBL-IFU-028) for complete system description, indications and warnings.



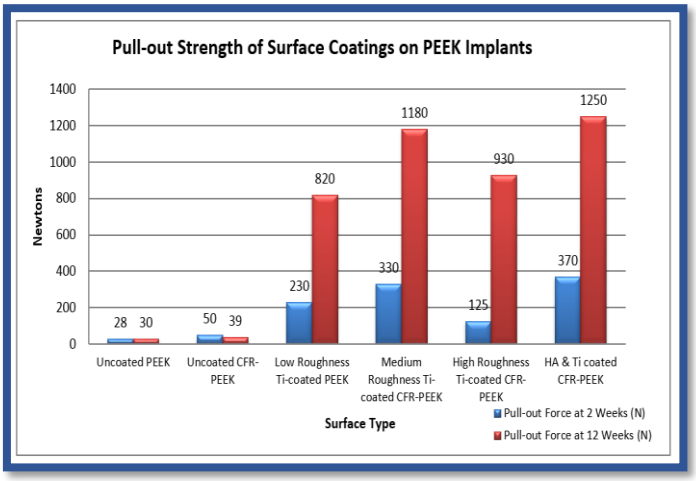




ShurFit® 2C OVERVIEW

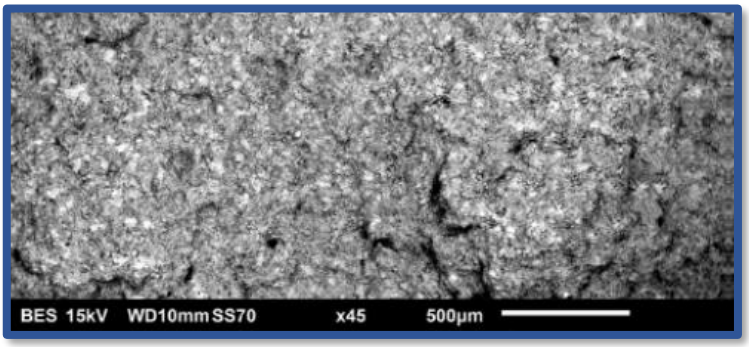


HA Coating on CP Titanium provides direct bony attachment to the implant surface (histologic image)

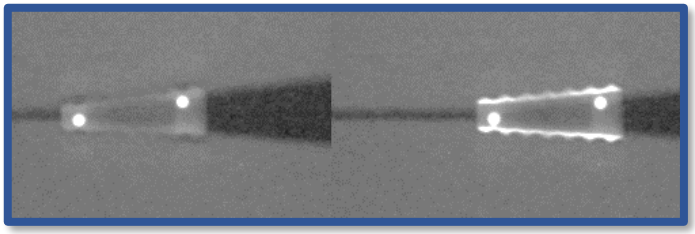


Best in Class Pull-Out Strength (N) Properties of HA + Ti Coating illustrated in head-to-head comparison of various coated PEEK surfaces [1]

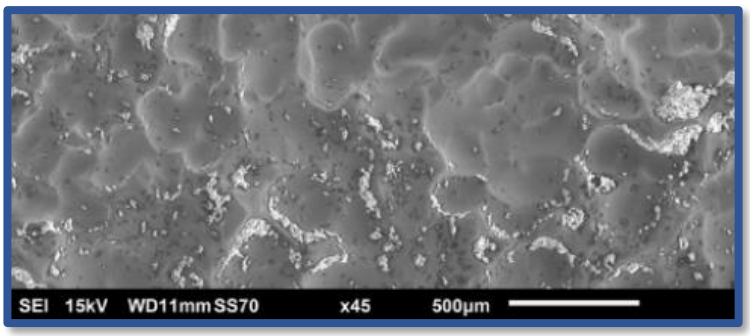
- Regardless of roughness variation, dual coating had best strength



Bone-mimicking roughness and bioactive HA layer (SEM image)



Improved visibility of endplates with 2C Coating demonstrated in polyurethane foam simulated bone (fluoroscopic image)



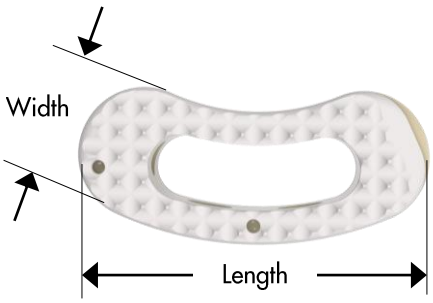
Typical competitor's etched titanium surface does **not** feature the same bone-mimicking roughness of the ShurFit® ACIF 2C coated surface (SEM image)

References:
(1) Stubinger, et al. J. Biomed Mater Res Part B. 2016; 104B:1182-91. Epub 2015 June 11.

IMPLANTS *(pre-packaged sterile)*

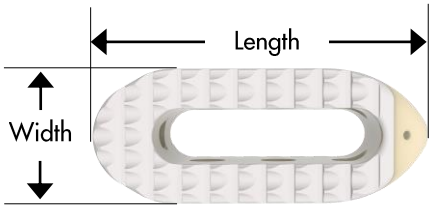
TLIF Curved, 0° (Set # 68-BK-0001T)

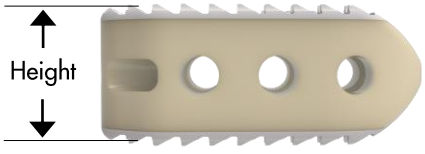
Item No.	TLIF, Curved, 0° (L x W x H)	Qty/Set
TLIF24-06P-2C *	24mm x 9mm x 6mm	By Request Only
TLIF24-07P-2C	24mm x 9mm x 7mm	3
TLIF24-08P-2C	24mm x 9mm x 8mm	3
TLIF24-09P-2C	24mm x 9mm x 9mm	3
TLIF24-10P-2C	24mm x 9mm x 10mm	3
TLIF24-11P-2C	24mm x 9mm x 11mm	3
TLIF24-12P-2C	24mm x 9mm x 12mm	3
TLIF24-14P-2C	24mm x 9mm x 14mm	3
TLIF24-16P-2C *	24mm x 9mm x 16mm	By Request Only
TLIF30-06P-2C *	30mm x 9mm x 6mm	By Request Only
TLIF30-07P-2C	30mm x 9mm x 7mm	3
TLIF30-08P-2C	30mm x 9mm x 8mm	3
TLIF30-09P-2C	30mm x 9mm x 9mm	3
TLIF30-10P-2C	30mm x 9mm x 10mm	3
TLIF30-11P-2C	30mm x 9mm x 11mm	3
TLIF30-12P-2C	30mm x 9mm x 12mm	3
TLIF30-14P-2C	30mm x 9mm x 14mm	3
TLIF30-16P-2C *	30mm x 9mm x 16mm	By Request Only



TPLIF Straight, 0° (Set # 68-BK-0002T)

Item No.	TPLIF, Straight, 0° (L x W x H)	Qty/Set
07-2907-2C	29mm x 11mm x 7mm	3
07-2908-2C	29mm x 11mm x 8mm	3
07-2909-2C	29mm x 11mm x 9mm	3
07-2910-2C	29mm x 11mm x 10mm	3
07-2911-2C	29mm x 11mm x 11mm	3
07-2912-2C	29mm x 11mm x 12mm	3
07-2913-2C	29mm x 11mm x 13mm	3
07-2914-2C	29mm x 11mm x 14mm	3
07-2915-2C *	29mm x 11mm x 15mm	By Request Only
07-2916-2C *	29mm x 11mm x 16mm	By Request Only

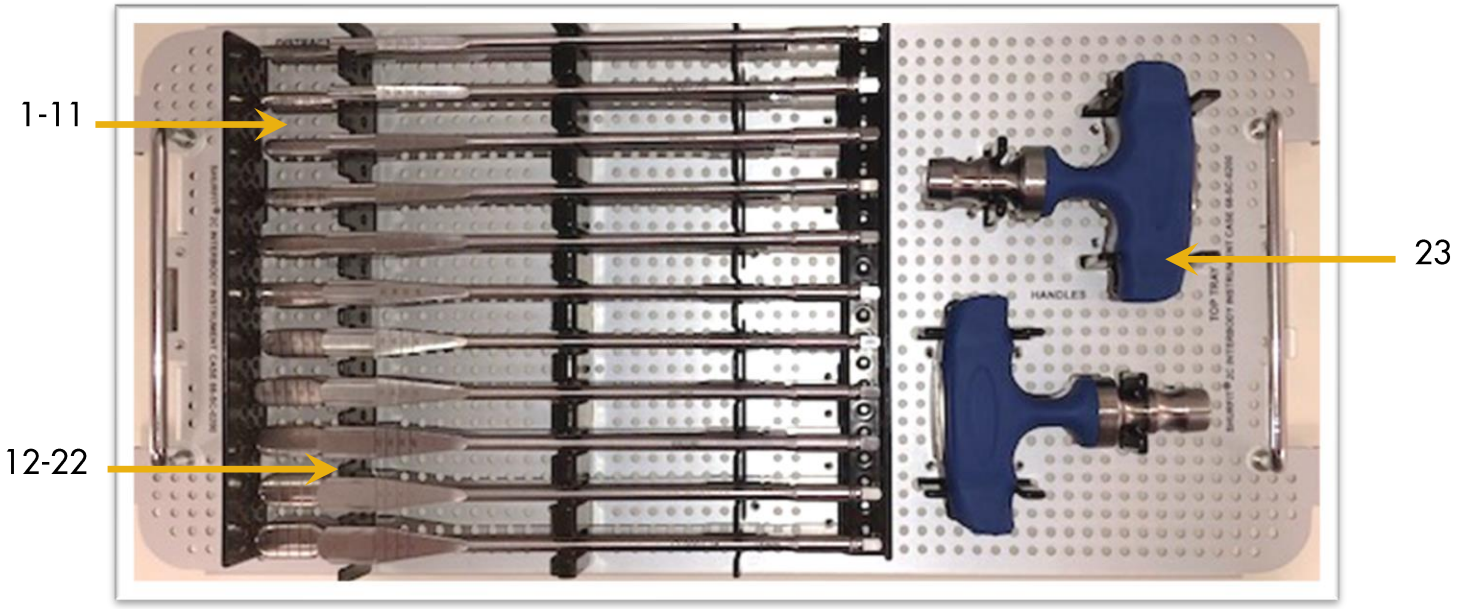




**** By Request Only***

Instrument Set - Distractors/Shavers

68-BK-0201 - TLIF Curved, 0°
68-BK-0202 - TPLIF Straight, 0°



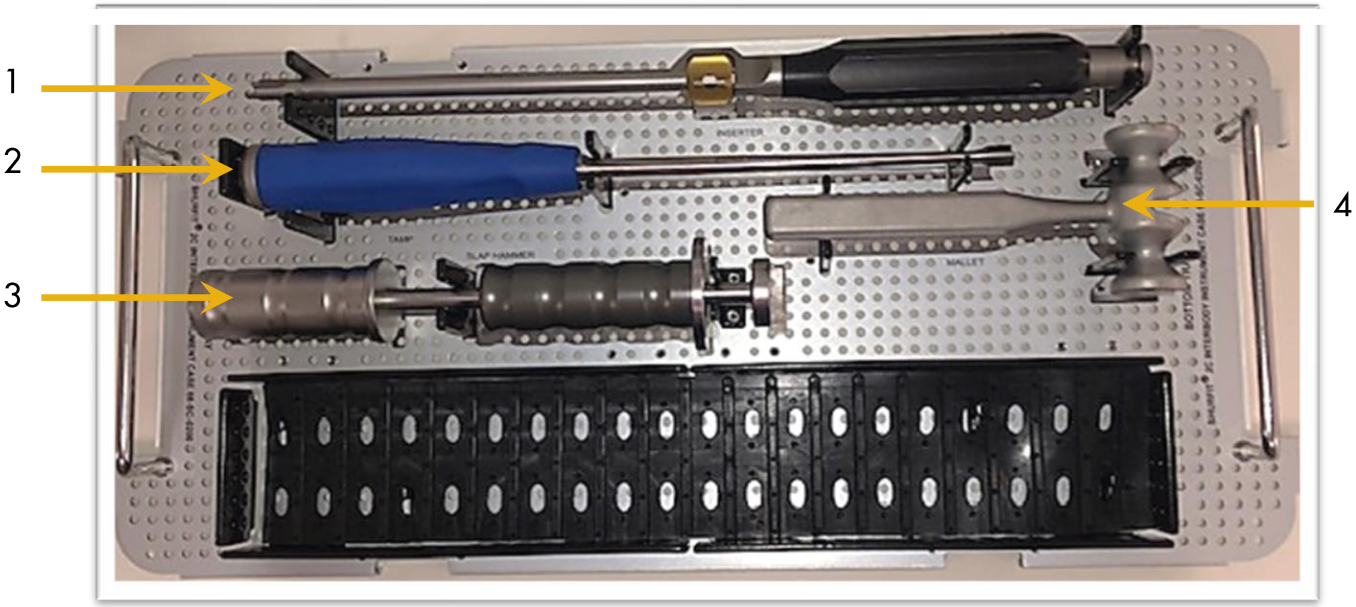
#	Item No.	Description	Qty
1	12-9002-06	Paddle Distractor, 6mm	1
2	12-9002-07	Paddle Distractor, 7mm	1
3	12-9002-08	Paddle Distractor, 8mm	1
4	12-9002-09	Paddle Distractor, 9mm	1
5	12-9002-10	Paddle Distractor, 10mm	1
6	12-9002-11	Paddle Distractor, 11mm	1
7	12-9002-12	Paddle Distractor, 12mm	1
8	12-9002-13	Paddle Distractor, 13mm	1
9	12-9002-14	Paddle Distractor, 14mm	1
10	12-9002-15*	Paddle Distractor, 15mm	1
11	12-9002-16*	Paddle Distractor, 16mm	1

#	Item No.	Description	Qty
12	12-9001-06	Paddle Shaver, 6mm	1
13	12-9001-07	Paddle Shaver, 7mm	1
14	12-9001-08	Paddle Shaver, 8mm	1
15	12-9001-09	Paddle Shaver, 9mm	1
16	12-9001-10	Paddle Shaver, 10mm	1
17	12-9001-11	Paddle Shaver, 11mm	1
18	12-9001-12	Paddle Shaver, 12mm	1
19	12-9001-13	Paddle Shaver, 13mm	1
20	12-9001-14	Paddle Shaver, 14mm	1
21	12-9001-15*	Paddle Shaver, 15mm	1
22	12-9001-16*	Paddle Shaver, 16mm	1
23	12-9003	T-Handles	2

*By Request Only

Instrument Set - Implantation

68-BK-0201 - TLIF Curved, 0°
68-BK-0202 - TPLIF Straight, 0°



#	Item No.	Description	Qty
1	12-CP-9012	Inserter	1
2	12-9004	Tam	1
3	12-9027	Slap Hammer	1
4	09-9043	Mallet	1

Instrument Set - Trials

68-BK-0201 - TLIF Curved, 0°

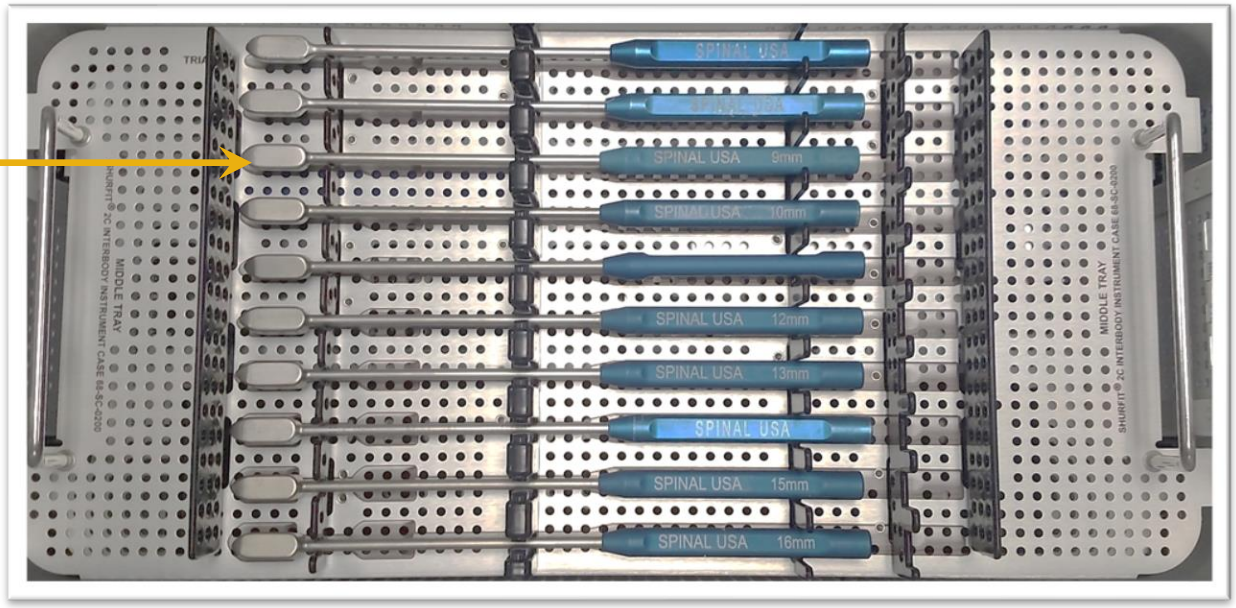
#	Item No.	Description	Qty
1	00-9003-06	TLIF Curved Trial, 0°, 30mm x 6mm	1
2	00-9003-07	TLIF Curved Trial, 0°, 30mm x 7mm	1
3	00-9003-08	TLIF Curved Trial, 0°, 30mm x 8mm	1
4	00-9003-09	TLIF Curved Trial, 0°, 30mm x 9mm	1
5	00-9003-10	TLIF Curved Trial, 0°, 30mm x 10mm	1
6	00-9003-11	TLIF Curved Trial, 0°, 30mm x 11mm	1
7	00-9003-12	TLIF Curved Trial, 0°, 30mm x 12mm	1
8	00-9003-14	TLIF Curved Trial, 0°, 30mm x 14mm	1
9	00-9003-16*	TLIF Curved Trial, 0°, 30mm x 16mm	1
10	00-9012-06	TLIF Curved Trial, 0°, 24mm x 6mm	1
11	00-9012-07	TLIF Curved Trial, 0°, 24mm x 7mm	1
12	00-9012-08	TLIF Curved Trial, 0°, 24mm x 8mm	1
13	00-9012-09	TLIF Curved Trial, 0°, 24mm x 9mm	1
14	00-9012-10	TLIF Curved Trial, 0°, 24mm x 10mm	1
15	00-9012-11	TLIF Curved Trial, 0°, 24mm x 11mm	1
16	00-9012-12	TLIF Curved Trial, 0°, 24mm x 12mm	1
17	00-9012-14	TLIF Curved Trial, 0°, 24mm x 14mm	1
18	00-9012-16*	TLIF Curved Trial, 0°, 24mm x 16mm	1

*By Request Only

Instrument Set - Trials

68-BK-0202 - TPLIF Straight, 0°

1-10



#	Item No.	Description	Qty
1	00-9006-07	TPLIF Straight Trial, 0°, 29mm x 7mm	1
2	00-9006-08	TPLIF Straight Trial, 0°, 29mm x 8mm	1
3	00-9006-09	TPLIF Straight Trial, 0°, 29mm x 9mm	1
4	00-9006-10	TPLIF Straight Trial, 0°, 29mm x 10mm	1
5	00-9006-11	TPLIF Straight Trial, 0°, 29mm x 11mm	1
6	00-9006-12	TPLIF Straight Trial, 0°, 29mm x 12mm	1
7	00-9006-13	TPLIF Straight Trial, 0°, 29mm x 13mm	1
8	00-9006-14	TPLIF Straight Trial, 0°, 29mm x 14mm	1
9	00-9006-15*	TPLIF Straight Trial, 0°, 29mm x 15mm	1
10	00-9006-16*	TPLIF Straight Trial, 0°, 29mm x 16mm	1

*By Request Only

SURGICAL TECHNIQUE

1 PATIENT POSITIONING

Place the patient in the prone position and drape in a manner consistent with surgical facility protocol. Utilizing A/P and lateral fluoroscopic imaging and palpation of the patient anatomy, identify and mark the affected level.

2 ENDPLATE PREPARATION

Create a skin incision at the targeted affected level(s) and dissect and retract the soft tissue.

Remove the inferior facet of the superior vertebrae with an osteotome, burr, or kerrison. Expose and resect the capsular portion of the ligamentum flavum. Excise the superior facet of the inferior vertebrae with an osteotome, burr, or Kerrison.

Repeat on the contralateral side for a bilateral PLIF.

Decompress the neural foramen and central spinal canal as necessary. Expose the posterolateral portion of the annular fibrosis and create an annular window to gain access to the intervertebral space.

Additional distraction can be achieved with Paddle Distractors (12-9002-XX). (Figure 1)

Utilize the Paddle Shavers to prepare the disc space and remove the superficial layers of the cartilaginous endplates (12-9001-XX). (Figure 2)

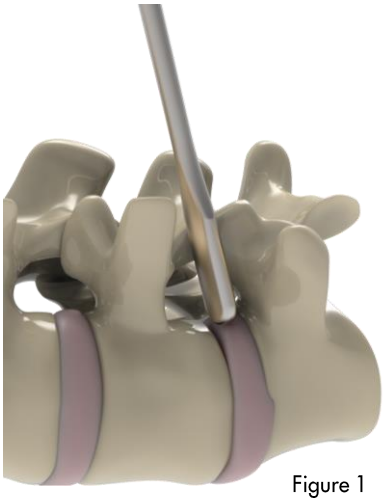


Figure 1

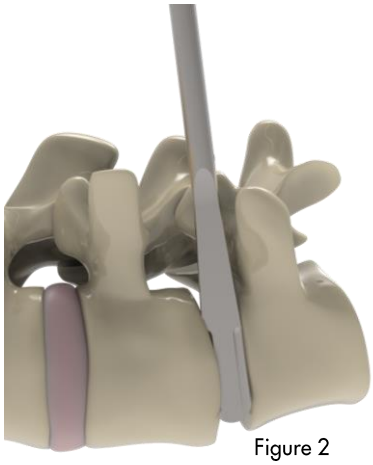


Figure 2

SURGICAL TECHNIQUE

3 IMPLANT SELECTION

At the surgeon's discretion, posterior distraction of the vertebral space may be performed.

Insert the appropriate Trial Sizer (00-9004-XX, 00-9005-XX, 00-9006-XX) into the annulotomy window and position within the disc space. (Figure 3)

Confirm proper positioning with A/P and lateral fluoroscopy.

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

A Slap Hammer (12-9027) may be used in positioning or removing the Trial Sizer.

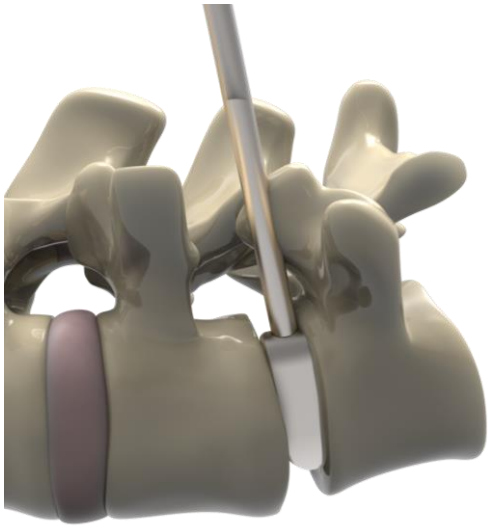


Figure 3

4 IMPLANT INSERTION

Based on the final Trial Sizer, attach the appropriate size implant onto the Inserter (12-CP-9012). (Figure 4)

Position the distal tips of the Inserter securely onto the sides of the implant. While holding the implant on the Inserter, rotate the gold knob clockwise (Figure 2) on the Inserter to thread implant onto the Inserter.

Note: Do not overtighten the Inserter to the implant.

Insert bone graft material to the large window of the implant.

Insert the implant into the disc space. Confirm proper positioning with A/P and lateral fluoroscopy.

Disengage the Inserter from the implant by rotating the gold knob counterclockwise until it is free from the implant. Final position of the implant can be achieved using the Tamp.

Confirm final implant position via A/P and lateral fluoroscopy.

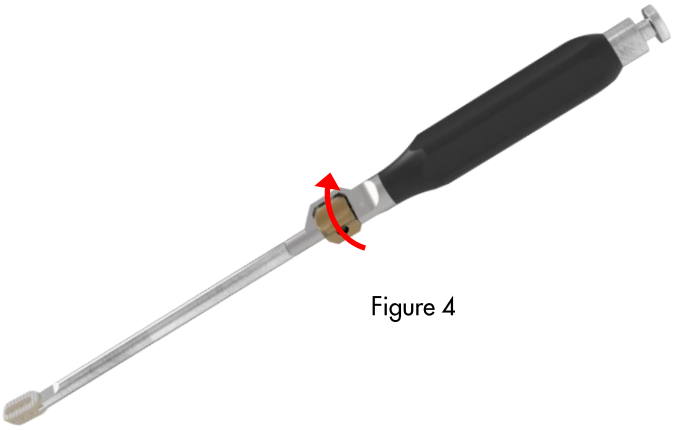
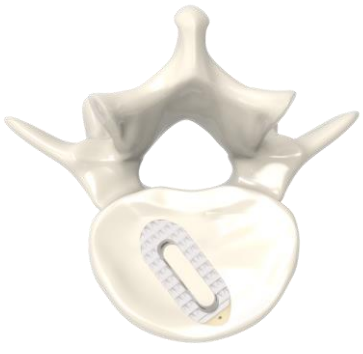
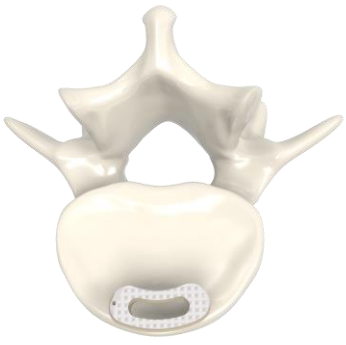


Figure 4



TPLIF



TLIF

SURGICAL TECHNIQUE

5 INSERTER ASSEMBLY/ DISASSEMBLY

Inserter Disassembly (for cleaning purposes)

1. While depressing the gold button on the handle, push the distal tip of the threaded shaft (Figure 5a) through the inserter until it exits from the top of the handle.

2. Using forceps or a needle holder, pull the threaded shaft (Figure 5b) from the handle and completely out of the Inserter.

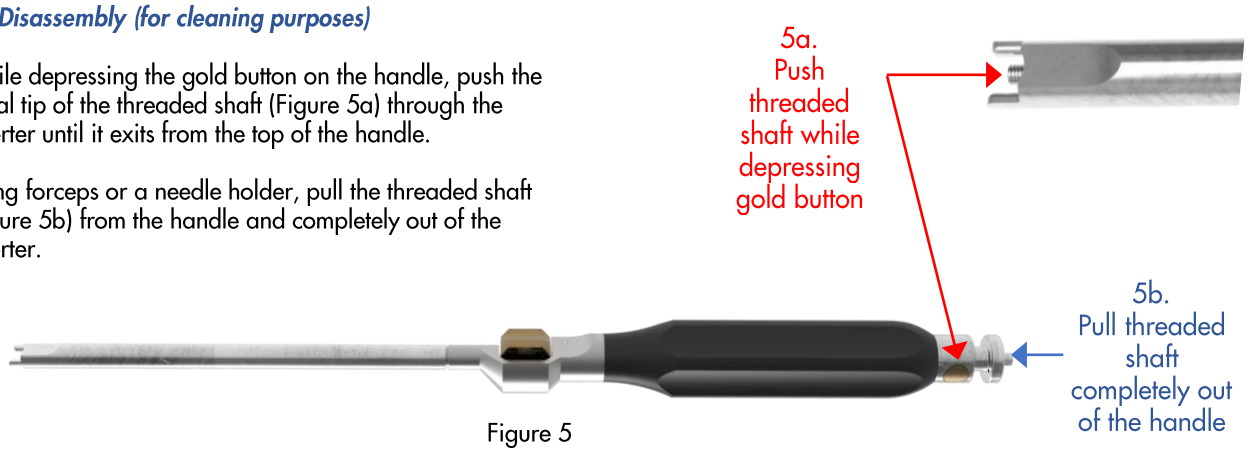


Figure 5

Inserter Assembly

1. Insert the distal tip of the threaded shaft into the handle and through the inserter. Align the flat on proximal tip of the threaded shaft to the line on the gold knob (Figure 6a).

2. Once the flat of the threaded shaft and the line on the gold knob are aligned, depress the gold button on the handle and push the threaded shaft through the handle and Inserter until it exits at the distal tip of the Inserter (Figure 6b).

   A slight turn of the gold knob and/or the threaded shaft may be required to properly align and seat the shaft within the Inserter.

3. Pull the distal tip of the threaded shaft until the proximal end is flush against the handle (Figure 6c).

   There will be an audible "click" when the threaded shaft is properly installed.

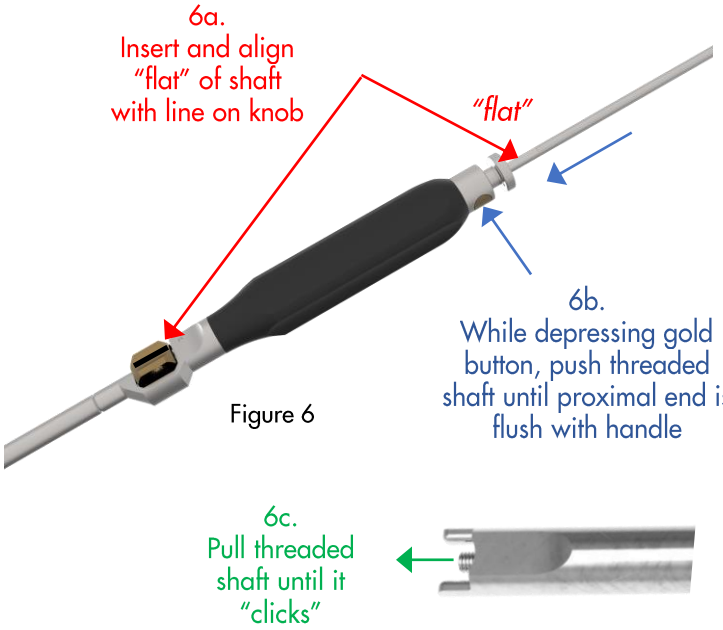


Figure 6

6 IMPLANT REMOVAL

If required, the implant can be removed using the Inserter and Slap Hammer. Position the distal tips of the Inserter securely onto the sides of the implant. While holding the implant on the Inserter, rotate the gold knob on the Inserter to tighten. Attach the Slap Hammer to the Inserter and remove the implant from the disc space.

INDICATIONS

CONTRAINDICATIONS

The ShurFit® TLIF *2C*, PLIF *2C*, LLIF *2C* and TPLIF *2C* 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 TLIF *2C*, PLIF *2C*, LLIF *2C* and TPLIF *2C* 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 bone grafting techniques should use the ShurFit TLIF *2C*, PLIF *2C*, LLIF *2C* and TPLIF *2C* 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.
    a. Physician note: Although the physician is the learned intermediary, the important medical information given in this document should be conveyed to the patient.
11. 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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