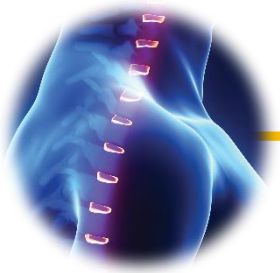
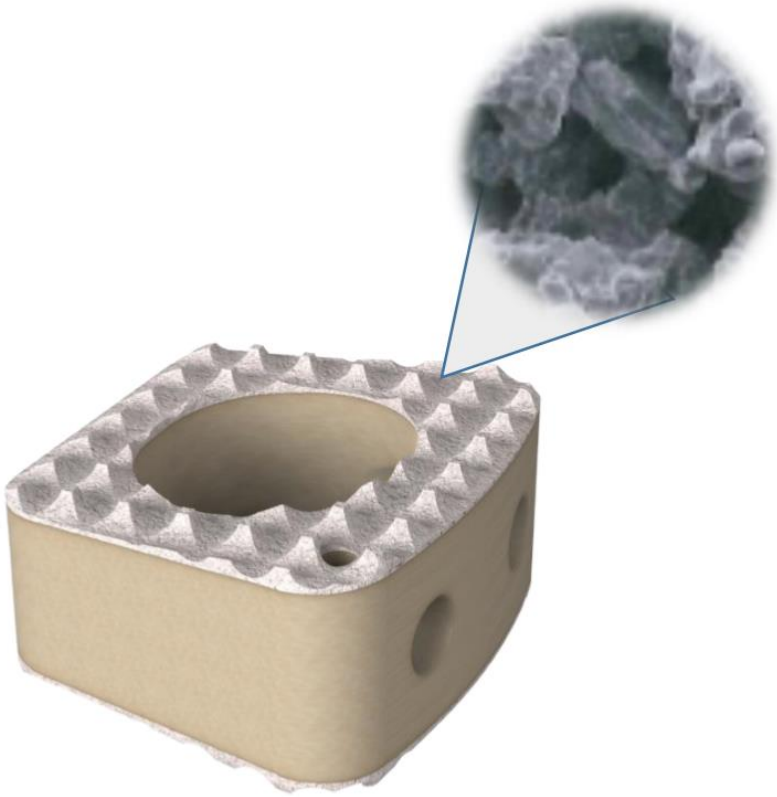


SURGICAL TECHNIQUE

PRECISION SPINE

SHURFIT® ACIF 2C

HA–CPTI COATED INTERBODY CAGES



PRECISION SPINE®

Discover the Difference

Made in the USA

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ShurFit® *ACIF 2C* OVERVIEW

The ShurFit ACIF *2C* Anterior Cervical Interbody Fusion System consists of implants with various heights to accommodate individual patient anatomy and graft material size. It is implanted from the anterior approach. 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, per ASTM F2026) and Tantalum (ASTM-F560), and coated with Commercially Pure Titanium in compliance with ASTM F1580 and Hydroxyapatite in compliance with ASTM F1185-03. The products are supplied clean and "STERILE".

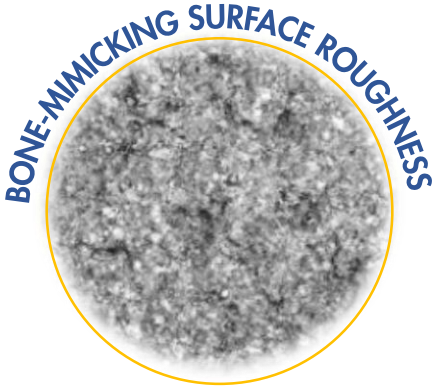
PRODUCT HIGHLIGHTS

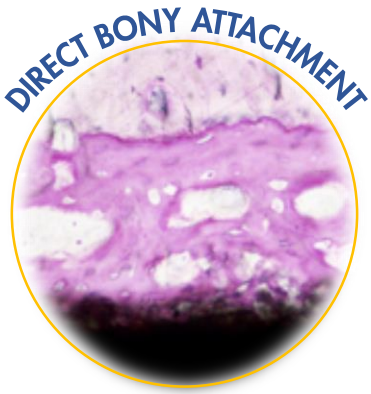
- Ti Plasma Coated surface provides enhanced stability, improved imaging properties and increased migration resistance
- HA Coating facilitates the formation of bone structure and may aid in more stable fixation
- Large contact area optimizes vertebral body supports and minimizes risk of subsidence
- Trapezoidal design allows for proper anterior placement
- Large graft area provides generous biological coverage
- Strategically placed tantalum markers (1.9mm from front edge, 1.8mm from side edge) facilitate radiographic implant positioning
- Aggressive tooth pattern resists expulsion

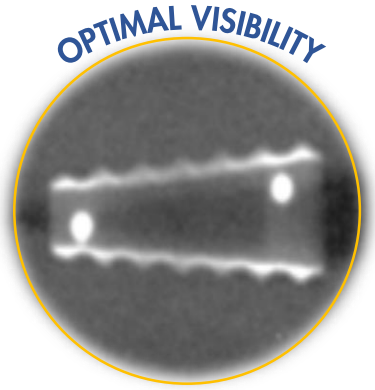
INDICATIONS

The ShurFit ACIF *2C* Anterior Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. ShurFit ACIF *2C* Anterior Cervical Interbody Fusion System implants are used to facilitate fusion in the cervical spine and are placed via an anterior approach at the C-3 to C-7 disc levels using autograft bone. Patients should have at least six weeks of non-operative treatment prior to treatment with an intervertebral fusion device. The device should be used with supplemental fixation.

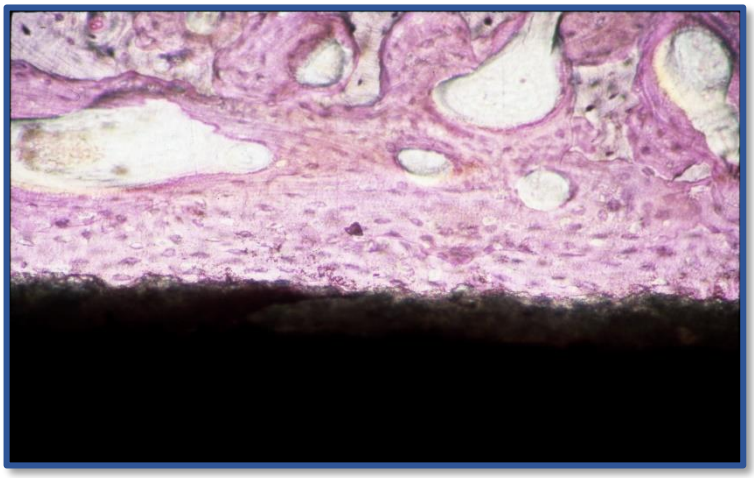
Please refer to package insert (LBL-IFU-023) for complete system description, indications and warnings.



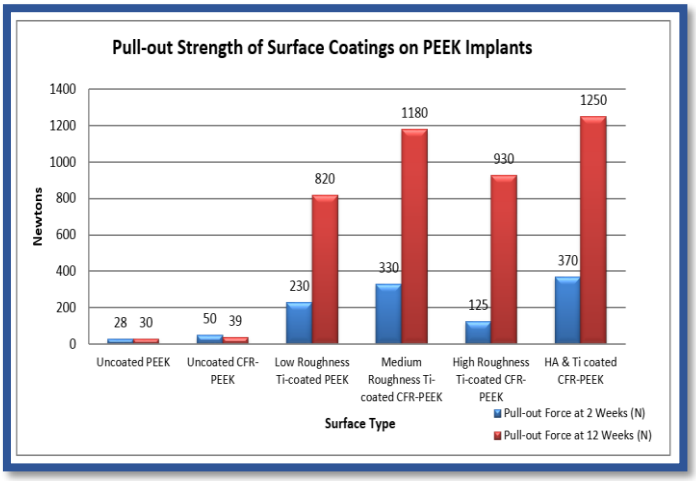




ShurFit® *ACIF 2C* OVERVIEW

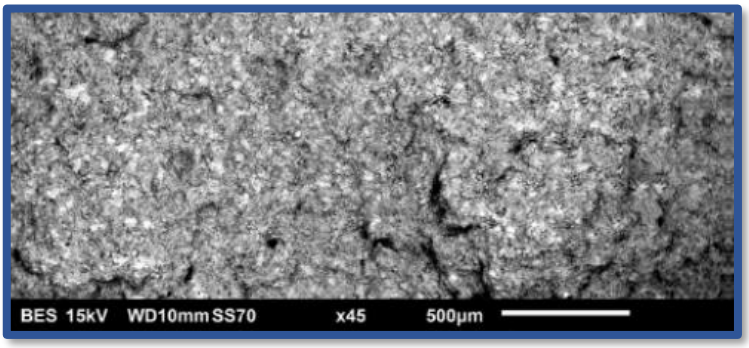


HA Coating on CP Titanium provides direct bony attachment to the implant surface (histologic image)

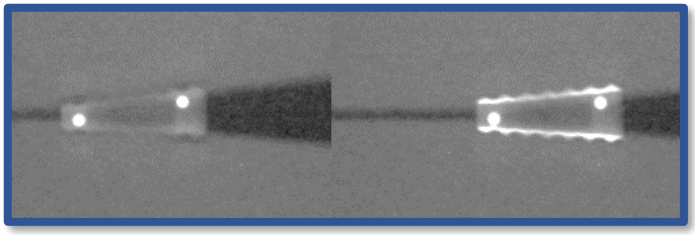


Best in Class Pull-Out Strength (N) Properties of HA + Ti Coating illustrated in head-to-head comparison of various coated PEEK surfaces [1]

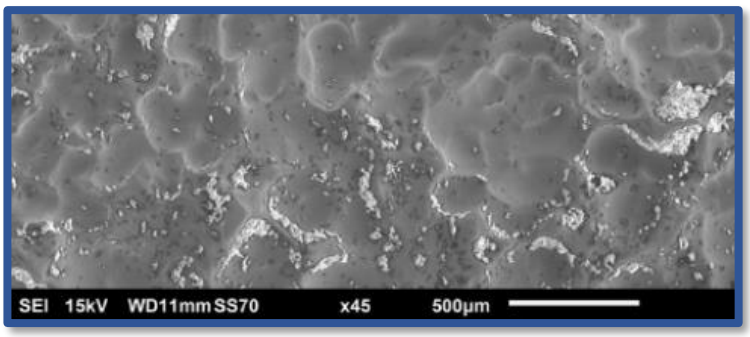
- Regardless of roughness variation, dual coating had best strength



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)

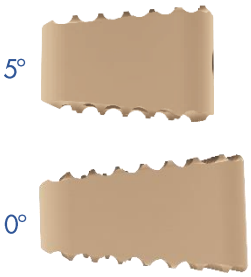
References:
(1) Stubinger, et al. J. Biomed Mater Res Part B. 2016; 104B:1182-91. Epub 2015 June 11.

IMPLANTS – Carrying Case

PART NUMBER 62-BK-0602

ShurFit® ACIF Implants

- 14mm Wide, 12mm Deep
- 16mm Wide, 14mm Deep
- 5-12mm Heights (1mm increments)
- 5° and 10° Lordotic Options

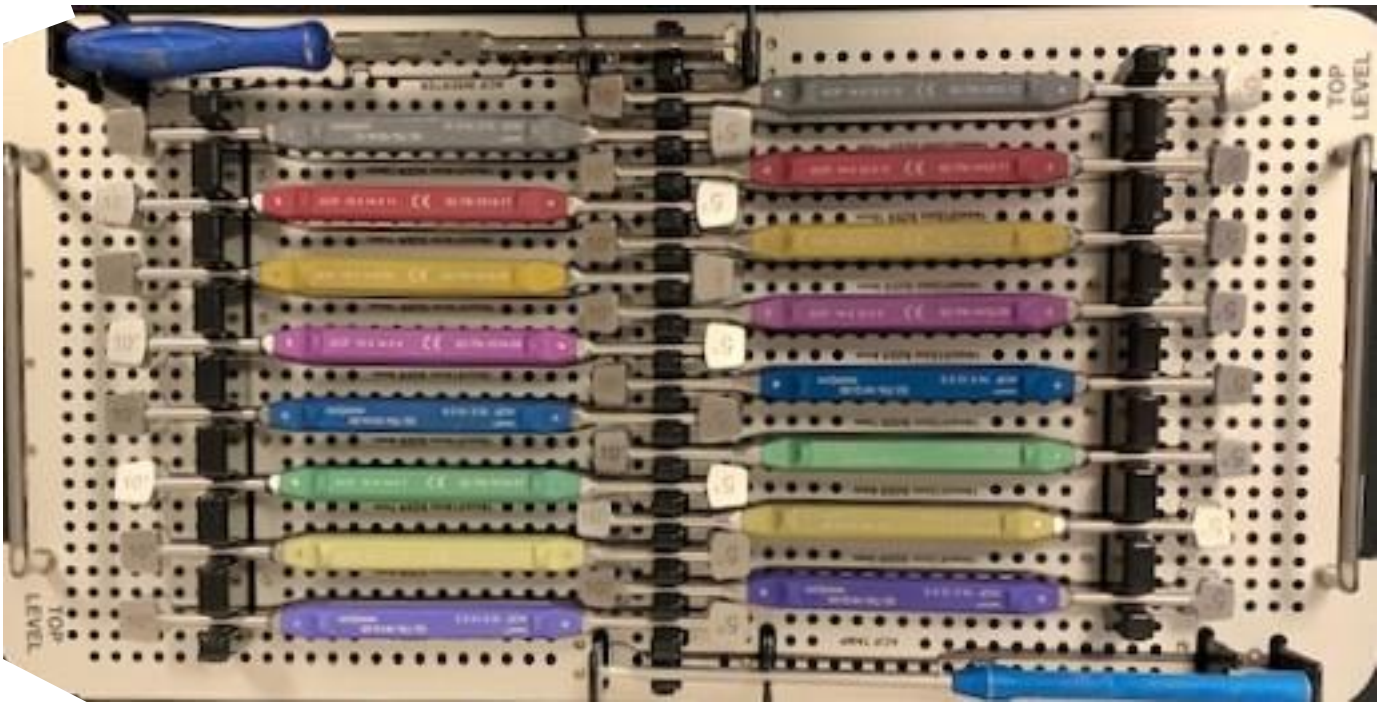


Item No.	Description	Qty
45-05-05P-2C	ACIF 2C 16x14mm 5 degree 5mm	1
45-05-06P-2C	ACIF 2C 16x14mm 5 degree 6mm	2
45-05-07P-2C	ACIF 2C 16x14mm 5 degree 7mm	3
45-05-08P-2C	ACIF 2C 16x14mm 5 degree 8mm	2
45-05-09P-2C	ACIF 2C 16x14mm 5 degree 9mm	2
45-05-10P-2C	ACIF 2C 16x14mm 5 degree 10mm	1
45-05-11P-2C	ACIF 2C 16x14mm 5 degree 11mm	1
45-05-12P-2C	ACIF 2C 16x14mm 5 degree 12mm	0
45-10-05P-2C	ACIF 2C 16x14mm 10 degree 5mm	1
45-10-06P-2C	ACIF 2C 16x14mm 10 degree 6mm	2
45-10-07P-2C	ACIF 2C 16x14mm 10 degree 7mm	3
45-10-08P-2C	ACIF 2C 16x14mm 10 degree 8mm	2
45-10-09P-2C	ACIF 2C 16x14mm 10 degree 9mm	2
45-10-10P-2C	ACIF 2C 16x14mm 10 degree 10mm	1
45-10-11P-2C	ACIF 2C 16x14mm 10 degree 11mm	1
45-10-12P-2C	ACIF 2C 16x14mm 10 degree 12mm	0

Item No.	Description	Qty
ACIF05-05P-2C	ACIF 2C 14x12mm 5 degree x 5mm	1
ACIF05-06P-2C	ACIF 2C 14x12mm 5 degree x 6mm	2
ACIF05-07P-2C	ACIF 2C 14x12mm 5 degree x 7mm	3
ACIF05-08P-2C	ACIF 2C 14x12mm 5 degree x 8mm	2
ACIF05-09P-2C	ACIF 2C 14x12mm 5 degree x 9mm	2
ACIF05-10P-2C	ACIF 2C 14x12mm 5 degree x 10mm	1
ACIF05-11P-2C	ACIF 2C 14x12mm 5 degree x 11mm	1
ACIF05-12P-2C	ACIF 2C 14x12mm 5 degree x 12mm	0
ACIF10-05P-2C	ACIF 2C 14x12mm 10 degree x 5mm	1
ACIF10-06P-2C	ACIF 2C 14x12mm 10 degree x 6 mm	2
ACIF10-07P-2C	ACIF 2C 14x12mm 10 degree x 7 mm	3
ACIF10-08P-2C	ACIF 2C 14x12mm 10 degree x 8 mm	2
ACIF10-09P-2C	ACIF 2C 14x12mm 10 degree x 9 mm	2
ACIF10-10P-2C	ACIF 2C 14x12mm 10 degree x 10 mm	1
ACIF10-11P-2C	ACIF 2C 14x12mm 10 degree x 11 mm	1
ACIF10-12P-2C	ACIF 2C 14x12mm 10 degree x 12 mm	0

INSTRUMENT TRAY

PART NUMBER 62-BK-01XX



Item No.	Description	Qty
ACIFS05	14x12mm Cervical Sizer 5mm	1
ACIFS06	14x12mm Cervical Sizer 6mm	1
ACIFS07	14x12mm Cervical Sizer 7mm	1
ACIFS08	14x12mm Cervical Sizer 8mm	1
ACIFS09	14x12mm Cervical Sizer 9mm	1
ACIFS10	14x12mm Cervical Sizer 10mm	1
ACIFS11	14x12mm Cervical Sizer 11mm	1
ACIFS12	14x12mm Cervical Sizer 12mm	1
45-905	16x14mm Cervical Sizer 5mm	1
45-906	16x14mm Cervical Sizer 6mm	1
45-907	16x14mm Cervical Sizer 7mm	1
45-908	16x14mm Cervical Sizer 8mm	1
45-909	16x14mm Cervical Sizer 9mm	1
45-910	16x14mm Cervical Sizer 10mm	1
45-911	16x14mm Cervical Sizer 11mm	1
45-912	16x14mm Cervical Sizer 12mm	1
02-9001	Inserter	1
02-9002	Tamp	1

SURGICAL TECHNIQUE

1 PATIENT POSITIONING

Position the patient in a supine position on a radiolucent operating table. Ensure that the neck of the patient is in a sagittally neutral position and supported with a cushion.

2 EXPOSURE & DISTRACTION

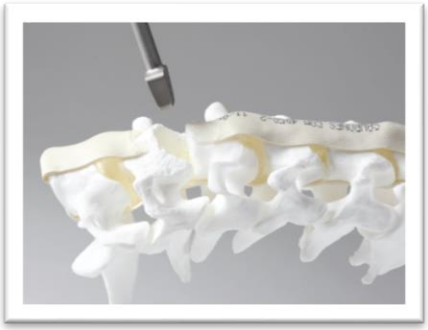
Obtain anterior exposure per surgeon preference. Perform segmental distraction. Distraction of the segment is essential for restoring disc height as well as for providing optimal access to the intervertebral space.

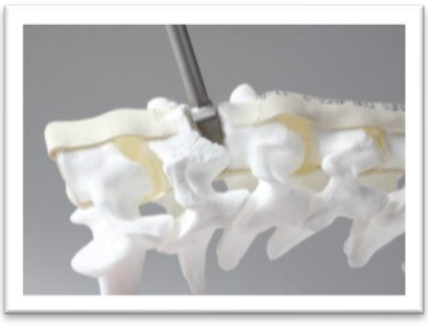
3 ENDPLATE PREPARATION

When the discectomy is complete, remove the superficial layers of the cartilaginous endplates to expose bleeding bone. This can be accomplished with a variety of instruments, such as osteotomes, scrapers, curettes and rasps. Adequate preparation of the endplates is important to enhance vascular supply to the fusion site.

4 TRIAL PLACEMENT

The selection of the trial implant is based on the height, width and depth of the intervertebral space, the preparation technique and the patient's anatomy. Choose either a Standard or Wide Footprint Cervical Sizer (ACIFSXX or 45-9XX) with the appropriate lordosis (5 or 10 degrees) and height (5-12mm). The Cervical Sizers are double sided. Ensure that the side with the appropriate lordosis is selected. The Cervical Sizers do not have a dedicated cranial or caudal surface. They can be inserted into the intervertebral disc space with either surface pointing cranially.





SURGICAL TECHNIQUE

5 IMPLANT INSERTION

Select the ACIF implant that corresponds to the footprint shape and height determined by the Cervical Sizer (02-9001). Rotate the knurled knob counter clockwise to expand the posts on the ACIF Inserter (02-9001).

Insert the two posts of the ACIF Inserter into the corresponding slots of the ACIF Implant. (Fig. 1)

Rotate the knurled knob of the ACIF Inserter clockwise to secure the ACIF Implant to the Inserter (Fig. 2 & 3).

Insert the ACIF Implant into the disc space (Fig. 4). If necessary, controlled, light hammering can be used to help advance the ACIF Implant into the intervertebral disc space.

Once the ACIF Implant is properly positioned, turn the knurled knob of the ACIF Inserter counter clockwise to release the Inserter from the Implant (Fig. 5).

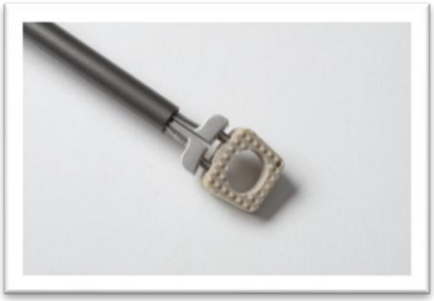


Figure 1

Figure 2

Figure 3

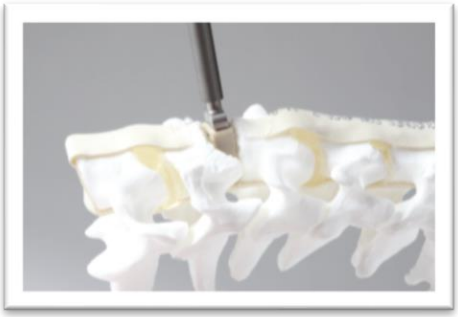


Figure 4

Figure 5

SURGICAL TECHNIQUE

6 IMPLANT POSITIONING

Verify the final ACIF Implant position relative to the vertebral bodies in the AP and Lateral directions with the help of an intraoperative x-ray.

The ACIF Implant has two tantalum markers incorporated in the implant to enable accurate assessment of the implant position (Fig. 8).

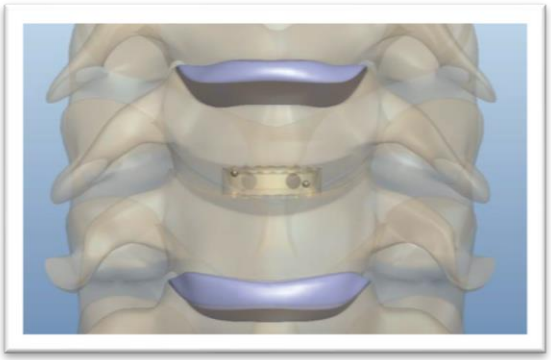


Figure 8

7 CLOSURE

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

The ShurFit® ACIF System surgical technique is a general guide for instrumentation. The surgeon should be familiar with anterior cervical fusion.

8 IMPLANT REMOVAL

If needed, the implant can be removed using the ShurFit ACIF Inserter (02-9001).

INDICATIONS

CONTRAINDICATIONS

The ShurFit® ACIF 2CAnterior Cervical Interbody Fusion System 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 ACIF 2C Anterior Cervical Interbody System 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 ACIF 2C Anterior Cervical Interbody System. 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.

NOTES

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