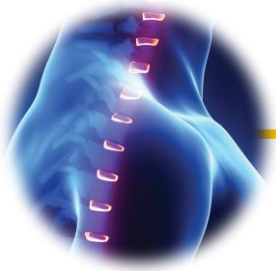


SURGICAL TECHNIQUE

PRECISION SPINE

SHURFIT®

CERVICAL INTERBODY CAGES

PRECISION SPINE®

Discover the Difference

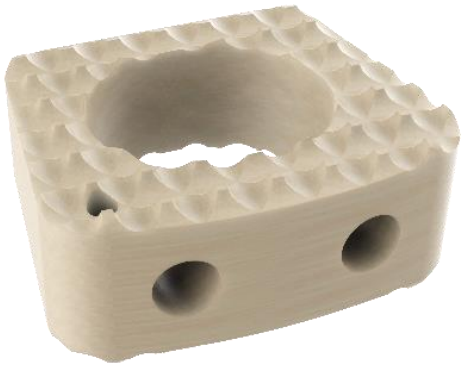
Made in the USA

TABLE OF CONTENTS

ShurFit® Anterior Cervical Interbody Fusion (ACIF)

ShurFit® *ACIF* OVERVIEW

The ShurFit 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. The products are supplied clean and "NON-STERILE".



PRODUCT HIGHLIGHTS

- 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

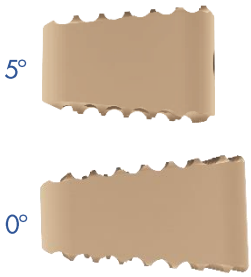
The ShurFit Anterior Cervical Interbody Fusion System is indicated for use in skeletally mature patients with degenerative disc disease (DDD) of the cervical spine at one disc level. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. ShurFit 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-006) for complete system description, indications and warnings.

IMPLANTS

ShurFit® ACIF Implants

- 14mm Wide, 12mm Deep
- 16mm Wide, 14mm Deep
- 18mm Wide, 15mm Deep
- 5-12mm Heights (1mm increments)
- 5 and 10 Degree Lordotic Options



Part Number	Description	Width & Depth
ACIF05-05P	Standard Cervical 5 degree x 5mm	14mm x 12mm
ACIF05-06P	Standard Cervical 5 degree x 6mm	14mm x 12mm
ACIF05-07P	Standard Cervical 5 degree x 7mm	14mm x 12mm
ACIF05-08P	Standard Cervical 5 degree x 8mm	14mm x 12mm
ACIF05-09P	Standard Cervical 5 degree x 9mm	14mm x 12mm
ACIF05-10P	Standard Cervical 5 degree x 10mm	14mm x 12mm
ACIF05-11P	Standard Cervical 5 degree x 11mm	14mm x 12mm
ACIF05-12P	Standard Cervical 5 degree x 12mm	14mm x 12mm
ACIF10-05P	Standard Cervical 10 degree x 5mm	14mm x 12mm
ACIF10-06P	Standard Cervical 10 degree x 6 mm	14mm x 12mm
ACIF10-07P	Standard Cervical 10 degree x 7 mm	14mm x 12mm
ACIF10-08P	Standard Cervical 10 degree x 8 mm	14mm x 12mm
ACIF10-09P	Standard Cervical 10 degree x 9 mm	14mm x 12mm
ACIF10-10P	Standard Cervical 10 degree x 10 mm	14mm x 12mm
ACIF10-11P	Standard Cervical 10 degree x 11 mm	14mm x 12mm
ACIF10-12P	Standard Cervical 10 degree x 12 mm	14mm x 12mm

Part Number	Description	Width & Depth
45-05-05P	Wide Cervical 5 degree 5mm	16mm x 14mm
45-05-06P	Wide Cervical 5 degree 6mm	16mm x 14mm
45-05-07P	Wide Cervical 5 degree 7mm	16mm x 14mm
45-05-08P	Wide Cervical 5 degree 8mm	16mm x 14mm
45-05-09P	Wide Cervical 5 degree 9mm	16mm x 14mm
45-05-10P	Wide Cervical 5 degree 10mm	16mm x 14mm
45-05-11P	Wide Cervical 5 degree 11mm	16mm x 14mm
45-05-12P	Wide Cervical 5 degree 12mm	16mm x 14mm
45-10-05P	Wide Cervical 10 degree 5mm	16mm x 14mm
45-10-06P	Wide Cervical 10 degree 6mm	16mm x 14mm
45-10-07P	Wide Cervical 10 degree 7mm	16mm x 14mm
45-10-08P	Wide Cervical 10 degree 8mm	16mm x 14mm
45-10-09P	Wide Cervical 10 degree 9mm	16mm x 14mm
45-10-10P	Wide Cervical 10 degree 10mm	16mm x 14mm
45-10-11P	Wide Cervical 10 degree 11mm	16mm x 14mm
45-10-12P	Wide Cervical 10 degree 12mm	16mm x 14mm

Part Number	Description	Width & Depth
45-CP-0505	Large Cervical 5 degree 5mm	18mm x 15mm
45-CP-0506	Large Cervical 5 degree 6mm	18mm x 15mm
45-CP-0507	Large Cervical 5 degree 7mm	18mm x 15mm
45-CP-0508	Large Cervical 5 degree 8mm	18mm x 15mm
45-CP-0509	Large Cervical 5 degree 9mm	18mm x 15mm
45-CP-0510	Large Cervical 5 degree 10mm	18mm x 15mm
45-CP-0511	Large Cervical 5 degree 11mm	18mm x 15mm
45-CP-0512	Large Cervical 5 degree 12mm	18mm x 15mm
45-CP-1005	Large Cervical 10 degree 5mm	18mm x 15mm
45-CP-1006	Large Cervical 10 degree 6mm	18mm x 15mm
45-CP-1007	Large Cervical 10 degree 7mm	18mm x 15mm
45-CP-1008	Large Cervical 10 degree 8mm	18mm x 15mm
45-CP-1009	Large Cervical 10 degree 9mm	18mm x 15mm
45-CP-1010	Large Cervical 10 degree 10mm	18mm x 15mm
45-CP-1011	Large Cervical 10 degree 11mm	18mm x 15mm
45-CP-1012	Large Cervical 10 degree 12mm	18mm x 15mm

INSTRUMENTS

ShurFit® ACIF Sizers

- Used to determine proper implant size
- Standard variations 14mm width x 12mm depth
- Wide variations 16mm width x 14mm depth
- Large variations 18mm width x 15mm depth
- All available 5mm to 12mm in 1mm increments;
- 5 degree and 10 degree
- See charts below for part numbers

Part Number	Description	Width & Depth
ACIFS05	Standard Cervical Sizer 5mm	14mm x 12mm
ACIFS06	Standard Cervical Sizer 6mm	14mm x 12mm
ACIFS07	Standard Cervical Sizer 7mm	14mm x 12mm
ACIFS08	Standard Cervical Sizer 8mm	14mm x 12mm
ACIFS09	Standard Cervical Sizer 9mm	14mm x 12mm
ACIFS10	Standard Cervical Sizer 10mm	14mm x 12mm
ACIFS11	Standard Cervical Sizer 11mm	14mm x 12mm
ACIFS12	Standard Cervical Sizer 12mm	14mm x 12mm

Part Number	Description	Width & Depth
45-905	Wide Cervical Sizer 5mm	16mm x 14mm
45-906	Wide Cervical Sizer 6mm	16mm x 14mm
45-907	Wide Cervical Sizer 7mm	16mm x 14mm
45-908	Wide Cervical Sizer 8mm	16mm x 14mm
45-909	Wide Cervical Sizer 9mm	16mm x 14mm
45-910	Wide Cervical Sizer 10mm	16mm x 14mm
45-911	Wide Cervical Sizer 11mm	16mm x 14mm
45-912	Wide Cervical Sizer 12mm	16mm x 14mm

Part Number	Description	Width & Depth
45-TN-5005	Large Cervical Sizer 5mm	18mm x 15mm
45-TN-5006	Large Cervical Sizer 6mm	18mm x 15mm
45-TN-5007	Large Cervical Sizer 7mm	18mm x 15mm
45-TN-5008	Large Cervical Sizer 8mm	18mm x 15mm
45-TN-5009	Large Cervical Sizer 9mm	18mm x 15mm
45-TN-5010	Large Cervical Sizer 10mm	18mm x 15mm
45-TN-5011	Large Cervical Sizer 11mm	18mm x 15mm
45-TN-5012	Large Cervical Sizer 12mm	18mm x 15mm

SHURFIT ACIF INSERTER

Used to place the implant in intervertebral space

- Part Number – 02-9001

SHURFIT ACIF TAMP

Used to assist with implant insertion

- Part Number – 02-9002

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

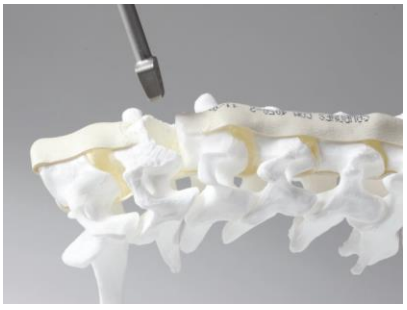
Obtain anterior exposure per surgeon preference. Perform segmental distraction. Distraction of the segment is essential for restoring disc height as well as for providing optimal access to the intervertebral space.

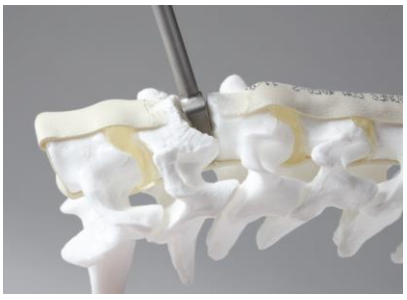
3 ENDPLATE PREPARATION

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, Wide or Large Footprint Cervical Sizer (ACIFSXX, 45-9XX or 45-TN-50XX) 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).

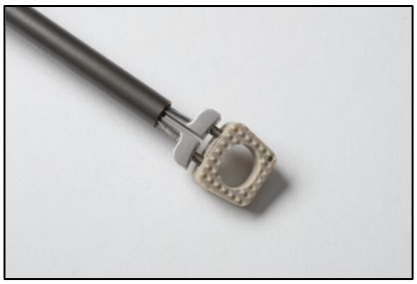


Figure 1

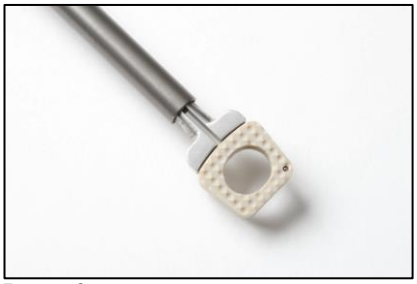


Figure 2

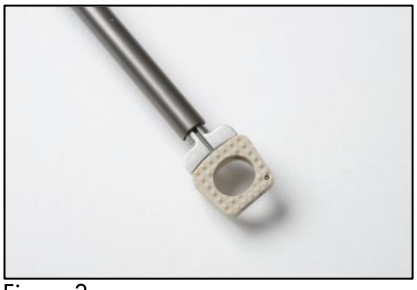


Figure 3

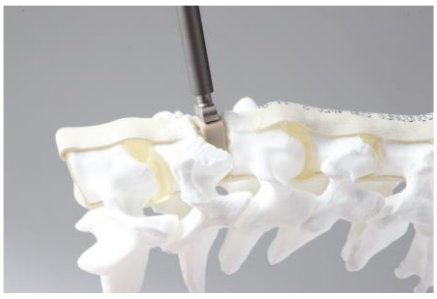


Figure 4

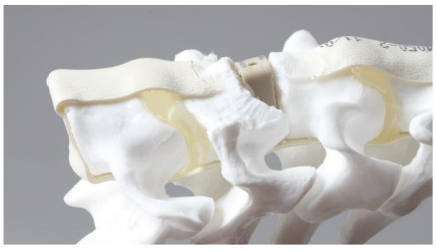


Figure 5

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).

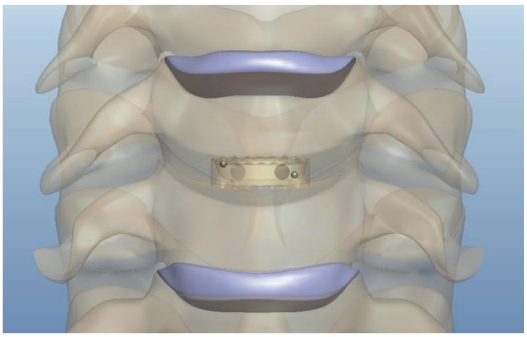


Figure 8

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).

IMPLANT & INSTRUMENT PART NUMBERS

IMPLANT CASE

PART No.	DESCRIPTION
ACIF05-05P	ACIF Cage Peek 5 degree x 5mm
ACIF05-06P	ACIF Cage Peek 5 degree x 6mm
ACIF05-07P	ACIF Cage Peek 5 degree x 7mm
ACIF05-08P	ACIF Cage Peek 5 degree x 8mm
ACIF05-09P	ACIF Cage Peek 5 degree x 9mm
ACIF05-10P	ACIF Cage Peek 5 degree x 10mm
ACIF05-11P	ACIF Cage Peek 5 degree x 11mm
ACIF05-12P	ACIF Cage Peek 5 degree x 12mm
ACIF10-05P	ACIF Cage Peek 10 degree x 5mm
ACIF10-06P	ACIF Cage Peek 10 degree x 6mm
ACIF10-07P	ACIF Cage Peek 10 degree x 7mm
ACIF10-08P	ACIF Cage Peek 10 degree x 8mm
ACIF10-09P	ACIF Cage Peek 10 degree x 9mm
ACIF10-10P	ACIF Cage Peek 10 degree x 10mm
ACIF10-11P	ACIF Cage Peek 10 degree x 11mm
ACIF10-12P	ACIF Cage Peek 10 degree x 12mm
45-05-05P	ACIF-Wide 5 degree x 5mm
45-05-06P	ACIF-Wide 5 degree x 6mm
45-05-07P	ACIF-Wide 5 degree x 7mm
45-05-08P	ACIF-Wide 5 degree x 8mm
45-05-09P	ACIF-Wide 5 degree x 9mm
45-05-10P	ACIF-Wide 5 degree x 10mm
45-05-11P	ACIF-Wide 5 degree x 11mm
45-05-12P	ACIF-Wide 5 degree x 12mm
45-10-05P	ACIF-Wide 10 degree x 5mm
45-10-06P	ACIF-Wide 10 degree x 6mm
45-10-07P	ACIF-Wide 10 degree x 7mm
45-10-08P	ACIF-Wide 10 degree x 8mm
45-10-09P	ACIF-Wide 10 degree x 9mm
45-10-10P	ACIF-Wide 10 degree x 10mm
45-10-11P	ACIF-Wide 10 degree x 11mm
45-10-12P	ACIF-Wide 10 degree x 12mm
45-CP-0505	Large 5 degree x 5mm
45-CP-0506	Large 5 degree x 6mm
45-CP-0507	Large 5 degree x 7mm
45-CP-0508	Large 5 degree x 8mm
45-CP-0509	Large 5 degree x 9mm
45-CP-1510	Large 5 degree x 10mm
45-CP-0511	Large 5 degree x 11mm
45-CP-0512	Large 5 degree x 12mm
45-CP-1005	Large 10 degree x 5mm
45-CP-1006	Large 10 degree x 6mm
45-CP-1007	Large 10 degree x 7mm
45-CP-1008	Large 10 degree x 8mm
45-CP-1009	Large 10 degree x 9mm
45-CP-1010	Large 10 degree x 10mm
45-CP-1011	Large 10 degree x 11mm
45-CP-1012	Large 10 degree x 12mm

INSTRUMENTS

PART No.	DESCRIPTION
HTR-02-1205	ACIF Rasp, Narrow, 2mm Stop (5mm Height) *
HTR-02-1206	ACIF Rasp, Narrow, 2mm Stop (6mm Height) *
HTR-02-1207	ACIF Rasp, Narrow, 2mm Stop (7mm Height) *
HTR-02-1208	ACIF Rasp, Narrow, 2mm Stop (8mm Height) *
HTR-02-1207	ACIF Rasp, Narrow, 2mm Stop (7mm Height) *
HTR-02-1208	ACIF Rasp, Narrow, 2mm Stop (8mm Height) *
HTR-02-1209	ACIF Rasp, Narrow, 2mm Stop (9mm Height) *
HTR-02-1210	ACIF Rasp, Narrow, 2mm Stop (10mm Height) *
HTR-02-1211	ACIF Rasp, Narrow, 2mm Stop (11mm Height) *
HTR-02-1212	ACIF Rasp, Narrow, 2mm Stop (12mm Height) *
HTR-45-1205	ACIF Rasp, Wide, 2mm Stop (5mm Height) *
HTR-45-1206	ACIF Rasp, Wide, 2mm Stop (6mm Height) *
HTR-45-1207	ACIF Rasp, Wide, 2mm Stop (7mm Height) *
HTR-45-1208	ACIF Rasp, Wide, 2mm Stop (8mm Height) *
HTR-45-1209	ACIF Rasp, Wide, 2mm Stop (9mm Height) *
HTR-45-1210	ACIF Rasp, Wide, 2mm Stop (10mm Height) *
HTR-45-1211	ACIF Rasp, Wide, 2mm Stop (11mm Height) *
HTR-45-1212	ACIF Rasp, Wide, 2mm Stop (12mm Height) *
ACIFS05	Cervical Sizer 5mm
ACIFS06	Cervical Sizer 6mm
ACIFS07	Cervical Sizer 7mm
ACIFS08	Cervical Sizer 8mm
ACIFS09	Cervical Sizer 9mm
ACIFS10	Cervical Sizer10mm
ACIFS11	Cervical Sizer 11mm
ACIFS12	Cervical Sizer12mm
45-905	ACIF-Wide 5mm Sizer
45-906	ACIF-Wide 6mm Sizer
45-907	ACIF-Wide 7mm Sizer
45-908	ACIF-Wide 8mm Sizer
45-909	ACIF-Wide 9mm Sizer
45-910	ACIF-Wide 10mm Sizer
45-911	ACIF-Wide 11mm Sizer
45-912	ACIF-Wide 12mm Sizer
45-TN-5005	ACIF-Large 5mm Sizer
45-TN-5006	ACIF-Large 6mm Sizer
45-TN-5007	ACIF-Large 7mm Sizer
45-TN-5008	ACIF-Large 8mm Sizer
45-TN-5009	ACIF-Large 9mm Sizer
45-TN-5010	ACIF-Large 10mm Sizer
45-TN-5011	ACIF-Large 11mm Sizer
45-TN-5012	ACIF-Large 12mm Sizer
02-9001	ACIF Inserter
02-9002	ACIF Tamp

* Special order

INDICATIONS

CONTRAINDICATIONS

The ShurFit® Anterior Cervical Interbody Fusion System (ACIF) 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 Anterior Cervical Interbody System (ACIF) 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 Anterior Cervical Interbody System (ACIF). 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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