CE 0086

PRECISION SPINE®

Instructions for Use
ShurFit® Interbody Fusion Devices

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

DISCLAIMER OF WARRANTY AND LIMITATION OF REMEDY

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DEVICE DESCRIPTION

The **ShurFit** Interbody Fusion Devices consist of implants with various widths, heights, lengths and bone screws to accommodate individual patient anatomy and graft material size. All components are manufactured from medical grade Polyetheretherketone (Peek Optima LT1) and Tantalum (ASTM-F560). The products are supplied clean and "NON-STERILE".

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 autogenuos autograft. Patients should have at least six months of non-operative treatment prior to treatment with a lumbar intervertebral fusion device.

The **AccuFit®** Anterior Lumbar Recessed Plate System is intended to be used only in anterior procedures in which an ALIF device of the same height is implanted. The **AccuFit** Anterior Lumbar Recessed Plate System is not meant for standalone use.

PRECAUTIONS:

Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the intervertebral body fusion device.

The implantation of the intervertebral body fusion device should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

All system implants are single-use only. Reuse of the device may result in the following:

1. Infection
2. Fracture / mechanical failure of the device
3. Inability to properly engage surgical instrumentation
4. Pyrogenic reaction

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 use

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 of 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.

PREOPERATIVE:

1. The surgeon should only consider utilizing the **ShurFit®** Interbody Fusion Device with those patients who meet the criteria in **Indications.**
2. The surgeon should avoid utilizing this device with those patients who have **Contraindications.**
3. The surgeon should make sure that all implants and instruments are unpacked, sterilized, and available prior to surgery.
4. The implants and instruments are provided non-sterile and must be cleaned and sterilized before use.
5. Implants and instruments should be inspected for surface flaws and scratches and should not be used in the presence thereof.
6. The surgeon should have a complete understanding of the surgical technique, design rationale, indications and contraindications.
7. The surgeon should have a complete understanding of the surgical technique manual for each approach, ALIF, LLIF, TLIF, T-PLIF, and PLIF.

INTRAOPERATIVE:

1. The instructions in any available applicable surgical technique manual should be carefully followed.
2. Damage to the nerves will cause loss of neurological functions. Extreme caution should be taken to avoid the spinal cord and nerve roots at all times.
3. Careful use of the implants and instruments should be taken. Misuse of the components may cause injury to the patient or operative personnel.
4. Autograft should be packed inside the device prior to insertion and around the device after insertion. Autograft must be placed in the area to be fused. The autograft must extend from the upper to the lower vertebrae to be fused.
5. Notching and scratching of implants should be avoided.
6. The **ShurFit** Interbody Fusion Device should be supported by anterior and/or posterior stabilization devices.

POSTOPERATIVE:

1. The physician's postoperative directions, warnings to the patient and the corresponding patient's compliance are extremely important.
2. For best possible results, patients should be counseled to avoid lifting, twisting, physical activities, smoking, consuming alcohol, and any other activity that would compromise or delay the healing process.
3. The patient should be warned about the limitation of bending at the point of spinal fusion.
4. The surgeon should instruct the patient regarding the amount and time frame after surgery of any weight bearing activity. The increased risk of bending, dislocation, and/or breakage of the implant devices, as well as an undesired surgical result are consequences of any type of early or excessive weight bearing, vibration motion, fall, jolts, or other movements preventing proper healing and/or fusion.
5. The removal of implants should be properly disposed of and are not to be reused under any circumstance.

PACKAGING AND STERILITY:

The **ShurFit** Interbody Fusion Devices will be supplied clean and non-sterile and must be sterilized prior to use. Remove all packaging before sterilization. Implants and instruments should be autoclave sterilized using one of the following validated cycle parameters.

Method	Cycle Type	Sterilization Temperature	Minimum Exposure Time
Steam	Gravity Displacement	270°F (132°C)	15 minutes
Steam	Pre-vacuum	270°F (132°C)	4 minutes

To assure maintenance of sterility we recommend:

- Utilization of a minimum drying time of 20 minutes in accordance with ANSI/AAMI ST79:2010, *Comprehensive guide to steam sterilization and sterility assurance in health facilities.*
- For USA: Only use FDA cleared sterilization wraps to enclose the sterilization tray.

MAGNETIC RESONANCE ENVIRONMENT:

The **ShurFit** Interbody Fusion Devices have not been evaluated for safety and compatibility in the Magnetic Resonance environment. The **ShurFit** Interbody Fusion Devices have not been tested for heating or migration in the Magnetic Resonance environment.

STORAGE INSTRUCTIONS

All products should be stored in a cool dry place.

HOW SUPPLIED

The required components and specialized instruments are supplied non-sterile in a container suitable for steam sterilization or individually packaged as replacement product. All components and instruments may be purchased independently.

CARE AND HANDLING

- All torque handles should be returned to the manufacturer for recalibration every six months.
- Please refer to ASTM standards such as F1744-96, "Standard Guide for Care and Handling of Stainless Steel Surgical Instruments" for additional information.
- Surgical instruments are subject to wear with normal usage. Instruments which have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments should be used only for their intended purpose.
- **Precision Spine®** recommends that all instruments be visually inspected for wear and disfigurement, as well as tested to ensure instruments are functioning properly prior to use. If instruments are discolored, have loose screws/pins, are out of alignment, are cracked or have other irregularities, **DO NOT USE**.

CLEANING AND DECONTAMINATION

- These instructions are to be followed prior to initial use and reprocessing of the instruments.
- Reprocessing the instruments using the methods described herein, will not limit the useful life of the instruments. The useful life of the product is typically determined by wear and damage due to use.
- Transport trays should be considered reusable devices, and inspected for visible soils and must be cleaned.
- **WARNING:** The following Cleaning instructions have been validated. Failure to follow all steps may result in an improperly cleaned and sterilized instrument (Non-Sterile).
- **CAUTION:** In order to preserve optimal efficiency and safety of the instruments, the following instructions must be followed.
    - The use of metallic brushes, scrub pads or other articles that are likely to damage the instrument must be avoided.
    - Chemicals, such as chlorine or soda as well as organic or ammoniated acids or solvents (e.g. Acetone) that are likely to damage the instrument, must not be used.
    - Mercurial solutions are not recommended, as they corrode metal parts.
    - If applicable, disassemble instruments prior to Cleaning. Articulated instruments must be opened in order to allow the cleaning of all interstices.
    - Immediately after the surgical procedure, disallowing organic debris to dry on the instruments, remove as much debris as possible from each instrument using a water moistened gauze pad or wipe, exchanging the gauze pad or wipe as it becomes soiled. Do not allow organic debris to dry.
    - Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions with warm tap water (35-40°C).
    - Immerse the instruments in the cleaning solution for a minimum of 10 minutes, activating any mechanisms 5X, so the enzymatic cleaner contacts all mated surfaces. Thoroughly scrub all instruments with a soft bristle cleaning brush while immersed in the enzymatic cleaning solutions. Be sure that thorough scrubbing also includes any lumens with an appropriately sized brush that contacts all surfaces. Change the soak solution after each utilization or if grossly soiled.
    - Rinse the instruments in warm tap water (35-40°C) for at least one minute.
    - Transfer the instruments into fresh enzymatic cleaning solution. Sonicate the instruments while immersed in the cleaning solution for a minimum of 15 minutes.
    - Thoroughly rinse all instruments and lumens with warm running water (35-40°C), for at least one minute each until flushing water runs clear. Use a hose or water jet to rinse any lumens, holes, or complex interfaces. Perform a second rinse with DI water, again using a hose or water jet to rinse any lumens, holes, or complex interfaces.
    - Dry with a sterile gauze, clean cloth and/or clean compressed air. Inspect instruments for cleanliness, function, and residual moisture. Any device that is not visually clean must be reprocessed.

LUBRICATION

To protect instruments from staining and rusting during sterilization and storage, they should be lubricated with a water-soluble, preserved lubricant after each cleaning. Since effective ultrasonic cleaning removes all lubricant, relubrication is important. The lubricant should contain a chemical preservative to prevent bacterial growth in the lubricant bath. The bath solution should be made with demineralized water. A lubricant containing a rust inhibitor helps prevent electrolytic corrosion of points and edges. Immediately after cleaning, instrument should be immersed for 30 seconds and allowed to drain off, not wiped off. A lubricant film will remain through the sterilization to protect them during storage.

SPECIAL NOTE FOR TORQUE LIMITING HANDLES

(This note only applies to customers who purchase Torque Limiting Handles).

The following are suggested guidelines for calibration cycles of Torque Limiting Handles. Note that these are general recommendations only and users are encouraged to determine specific calibration cycles for each product depending on their particular situation or usage. Return product after six months of use or, after 150 autoclave cycles or, after approximately 3000 actuations (Clicks) whichever comes first.

MATERIAL SPECIFICATION

All components are manufactured from Ti-6Al-4V titanium alloy (ASTM F136), medical grade Polyetheretherketone (Peek Optima LT1) and Tantalum (ASTM-F560). The products are supplied clean and "NON-STERILE".

CLINICAL HISTORY

These instructions for use are based upon current experience. The physician may wish to vary the procedure in accordance with clinical judgment.

PRODUCT COMPLAINTS:

Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to **Precision Spine®**. If any of the implants or instruments "malfunction" (i.e. do not meet any of their performance specifications or does not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, **Precision Spine** should be notified immediately by phone, fax or written correspondence. When filing a complaint, please provide the product description, product number, lot number, your name and address, and the nature of the complaint.

ADDITIONAL INFORMATION

The surgical technique guides for the implantation of the **ShurFit®** Interbody Fusion Devices are available upon request. If further information is required, please contact the manufacturer.

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			**RX only**
SEE PACKAGE INSERT FOR LABELING LIMITATIONS	NOT STERILE	SINGLE USE ONLY	SALE BY PHYSICIAN PRESCRIPTION FOR USA ONLY
			
MANUFACTURED BY			