Distributor Name -

Distributor Address -

Phone Number:

Fax:

Distributor Email Address:

After Hours Phone Number:

Operation Date:

Instruments /Procedure

Implant System:

Manufactured by:
Orthofix
3451 Plano Parkway
Lewisville, TX 75056
www.orthofix.com

Surgeon:

Hospital:

Patient:

Implant Label

Catalog Number	Lot#	Item Name	Single Use Item	QTY	HOSP IN	HOSP OUT

CSSD Count _____ Date _____

PILLAR® SA PTC Spacer System

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the PILLAR® SA PTC Spacer System were implanted in your body. Because of this, you must be aware of the following information.

GENERAL INFORMATION

Name and Model of the device

The PILLAR SA PTC Spacer System is comprised of a variety of implants that have a PEEK core with integrated porous titanium end plates. The implants incorporate integrated anterior screw holes to allow for medial placement of bone screws as well as a titanium plate for securing the bone screws once in place. The implants are designed with a roughened surface on the inferior and superior faces of the implant to provide increased stability and help prevent anterior/posterior movement of the device.

The PILLAR SA PTC Spacer System is intended for intervertebral body fusion to aid in the surgical correction of the spine and is implanted using an anterior approach. The PILLAR SA PTC spacers are provided sterile. The cover plate, screws and instruments are provided non-sterile and require sterilization prior to use. The PILLAR SA PTC implants are designed to be used with PILLAR SA PEEK Spacer System instrumentation.
The implants are not compatible with components from any other manufacturer's system.

What is the device for?

The PILLAR SA PTC Spacer System is indicated for spinal fusion procedures in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1).

Kind of patient on whom the device is intended to be used

The PILLAR SA PTC Spacer System is indicated for spinal fusion procedures in skeletally mature patients with Degenerative Disc Disease (DDD) at one or two contiguous levels in the lumbar spine (L2-S1). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. DDD patients may also have up to Grade 1 spondylolisthesis at the involved levels. These patients may have had a previous non-fusion surgery at the involved level(s).

The PILLAR SA PTC Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft.

The PILLAR SA PTC Spacer System is intended for use with four of the titanium alloy screws provided with the system. If the physician chooses to use fewer than four of the provided screws then supplemental fixation must be used to augment stability. As an example, a supplemental fixation system that may be used is the Orthofix Firebird® Spinal Fixation System.

Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the PILLAR SA PTC Spacer System.

Special operating instructions for the use of the device
There are no special operating instructions for the patient.

Intended performance of the device
The PILLAR SA PTC Spacer System is intended for intervertebral body fusion to aid in the surgical correction of the spine and is implanted using an anterior approach.

Side Effect

Potential adverse effects include, but are not limited to:

- Failure of the device to provide adequate mechanical stability.
- Loss of fixation of the implant.
- Device component failure.
- Migration or bending of the device.
- Loss of bony alignment.
- Non-union.
- Fracture of bony structures.
- Resorption without incorporation of any bone graft utilized.
- Immunogenic response to the implant materials.

Risk that can remain despite preventive measure
Refer to Side Effects

Warnings about risk that may arise from the use of the device

- Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery.
- No implant can be expected to withstand the unsupported stresses of full weight bearing. The size, shape and condition of the human bones are also contributing factors to the success of the surgery
- The PILLAR SA PTC Spacer System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of PILLAR SA PTC Spacer System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury

Precautions and other measure to be taken by the patent or a health professional

- Postoperative care is important. The patient should be instructed in the limitations of the implant and should be cautioned regarding weight bearing and body stress on the device prior to secure bone healing.
- 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 it is a technically demanding procedure presenting a risk of serious injury to the patient.
- As with any major surgical procedure, there are risks involved in orthopedic surgery. Infrequent operative and postoperative complications known to occur are: early or late infection, which may result in the need for additional surgeries, damage to blood vessels, spinal cord or peripheral nerves, pulmonary emboli, loss of sensory and/or motor function, impotence, permanent pain and/or deformity. In rare instances, some complications may be fatal.

Regular Exams, check and/or care of the device

Routine follow-up after implantation is by the surgeon's decision. Usually, there are visits to check the fusion achieved after surgery. This happens in the first few weeks after surgery. Imaging is commonly done, according to the surgeon's post-operative guidelines. These are done until time of fusion. Once healed, follow-up checks are done according to the surgeon's decision.

Symptoms that could indicate that the device is not functioning as it should

Some symptoms can indicate that the device is not functioning as it should. These include, among others (but not limited to), lasting pain, device component fracture, loss of fixation, non-union, and fracture of the vertebra, neurological injury, and vascular or visceral injury.

What to do if you suspect the device is malfunctioning

If you have any of the symptoms described above, contact your primary surgeon. If he/she is not available, contact a trained surgeon. Please seek medical assessment if a surgeon is not available.

Expected lifecycle of the device, what influences it, and precautions to take

The length of the treatment phase until acceptable fusion is achieved is dependent on several factors including – surgical technique, type of bone graft, patient health, compliance, etc. Consequently, the prediction of expected life time of an implant is subjective. It also depends on if you follow the indications given in the section "Precautions and other measures to be taken by the patient or a health professional". This section contains precautions and other measures to take at, or near, the end of the expected device lifetime as well.

Other cases in which the patient should contact a health professional in relation to the device

Refer to Symptoms

Materials and substances included in the device

The PILLAR SA PTC Spacer System implants are made from PEEK (Polyetheretherketone per ASTM F2026) and titanium material (ASTM F136).

Any residues from production that could put the patient at risk

There are no manufacturing residuals that could pose a risk to the patient. It is known that the production process may introduce residues, contaminants and additives with potential toxicity. The eventual presence of these substances does not reach toxic levels. In addition, a final cleaning stage is capable of further reducing these substances under the level of concern.

Important note:

Please report any serious problem with the PILLAR SA PTC Spacer System. You must contact Orthofix Inc and the Therapeutic Goods Administration.

Orthofix Inc

Orthofix Inc., 3451 Plano Parkway, Lewisville, TX 75056, USA.
Telephone: 1-214-937-3199 or 1-888-298-5700
E-mail: complaints@orthofix.com

Therapeutic Goods Administration:

https://www.tga.gov.au

(Please click on “Consumers”, then click on button “Report a problem or side effect” and then follow the instructions reported in “I want to report a problem with a medical device (adverse event)” section.)