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 PEEK Spacer System

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the PILLAR® SA PEEK 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 PEEK Spacer System is comprised of a variety of implants manufactured from PEEK (Polyetheretherketone) as described by ASTM F2026 with tantalum markers as described by ASTM F560. The implants are available in multiple footprints, a variety of heights, and two angles of lordosis: 7° and 12°. The implants incorporate integrated anterior screw holes to allow for medial placement of screws, as well as a titanium plate for securing the screws once in place. The superior and inferior surfaces of the implant have a pattern of ripples that provide increased stability and help prevent movement of the device. The PILLAR SA PEEK Spacer System is provided non-sterile.

What is the device for?

The PILLAR SA PEEK Spacer System is indicated for use with bone graft (autograft bone or allogenic bone graft composed of cancellous or corticocancellous bone graft) in patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1.

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

The PILLAR SA PEEK Spacer System is indicated for use with bone graft (autograft bone or allogenic bone graft composed of cancellous or corticocancellous bone graft) in patients with degenerative disk disease (DDD) at one or two contiguous levels from L2 to S1. These DDD patients may have up to Grade I Spondylolisthesis or retrolisthesis at the involved levels. DDD is defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment. Patients with previous non-fusion spinal surgery at the treated level may be treated.

The PILLAR SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. 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, the supplemental fixation system that may be used is the Orthofix Firebird Spinal Fixation System.

The PILLAR SA PEEK Spacer System must be used with autograft or allogenic bone graft composed of cancellous or corticocancellous bone graft.

When used as a Partial Vertebral Body Replacement (VBR) Device:
The PILLAR SA PEEK Spacer System is indicated for use in the thoracolumbar spine (T1-L5) for partial replacement (i.e., partial vertebrectomy) of a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body. The PILLAR SA PEEK Spacer System is also indicated for treating fractures of the thoracic and lumbar spine.

The PILLAR SA PEEK Spacer System is designed to restore the biomechanical integrity of the anterior, middle and posterior spinal column, even in the absence of fusion for a prolonged period of time. The PILLAR SA PEEK Spacer System is intended to be used with autograft or allograft.

The PILLAR SA PEEK Spacer System is intended for use with the four titanium alloy screws provided with the device. 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, the supplemental fixation that may be used is the Orthofix Firebird Spinal Fixation 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 PEEK Spacer System provides fixation within the intervertebral disc space with Bone Screws and a locking Cover Plate to prevent screw back-out.

Side Effect

Potential adverse events 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.
- The size and shape of human bones present limiting restrictions on the size and strength of implants No implant can be expected to withstand the unsupported stresses of full weight bearing.
- The PILLAR SA PEEK 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 PEEK 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.

- 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. Rarely, 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 PEEK Spacer System implants are made from PEEK (ASTM F2026) and titanium material (ASTM F560).

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 PEEK 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.)