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 _____

FORZA® PEEK Spacer System Intervertebral Body Fusion Device

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the FORZA® 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 FORZA PEEK Spacer System is comprised of a variety of implants manufactured from polyetheretherketone (PEEK) as described by ASTM F2026 with tantalum markers as described by ASTM F560. FORZA Spacer System implants are offered in two geometric shapes – straight and curved, and offered in parallel and lordotic profiles to restore the natural curvature of the spine. The implants can be used in single placement or in pairs. Both the curved and straight implants feature anti-migration ripples on both the inferior and superior surfaces to provide increased stability and help prevent anterior/posterior movement of the device

What is the device for?

The FORZA 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. The FORZA Spacer System is intended for intervertebral body fusion to aid in the surgical correction and stabilization of the spine and are implanted using a posterior approach. The FORZA Spacer System is not intended to be used as a stand-alone device. The FORZA Spacer System must be used with a supplemental fixation system.

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

The FORZA 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.

Special operating instructions for the use of the device

There are no special operating instructions for the patient.

Intended performance of the device

FORZA Spacer System implants are offered in two geometric shapes – straight and curved, and offered in parallel and lordotic profiles to restore the natural curvature of the spine. The implants can be used in single placement or in pairs. Both the curved and straight implants feature anti-migration ripples on both the inferior and superior surfaces to provide increased stability and help prevent anterior/posterior movement of the device.

Side Effect
Potential adverse events include, but are not limited to:

1. Failure of the device to provide adequate mechanical stability.
2. Loss of fixation of the implant.
3. Device component failure.
4. Migration or bending of the device.
5. Loss of bony alignment.
6. Non-union.
7. Fracture of bony structures.
8. Resorption without incorporation of any bone graft utilized.
9. 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
Postoperative care is important. Be aware of the limitations of the implant and use caution regarding weight bearing and body stress on the device prior to secure bone healing.

Precautions and other measure to be taken by the patent or a health professional
The FORZA® PEEK Spacer System has not been evaluated for safety and compatibility in the Magnetic Resonance (MR) environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of FORZA PEEK Spacer System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 the 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, 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 that device is malfunction
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 lifetime of the device, what influences it, and precautions to take
The implant is intended to remain implanted permanently.

Other cases in which the patient should contact a health professional in relation to the device
Refer to Symptoms that could indicate that the device is not functioning as it should.

Materials and substances included in the device
FORZA® Spacer System implants are made of PEEK (Polyetheretherketone), as described by ASTM F2026, tantalum markers as described by ASTM F560.

Any residues from production that could put the patient at risk
FORZA® Spacer implants have been evaluated for the presence of manufacturing residuals that could pose a risk to the patient. These evaluations determined that there are no residual materials present at toxic levels on finished devices. It is known that the production process may introduce residues, contaminants, and additives with potential toxicity. All FORZA® Spacer System implants undergo validated cleaning processes at multiple points in the manufacturing process to reduce the presence of residual materials below the level of concern.

Important Note:
Please report any serious problem with the FORZA® PEEK Spacer System. You must contact Orthofix Inc. and the Therapeutic Goods Administration.

Orthofix
3451 Plano Parkway, Lewisville, TX 75056

Tel: 1-214-937-3199 or 1-888-298-5700

Email: 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.)