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® XP Expandable Spacer System

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the FORZA® XP Expandable 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® XP Expandable Spacer System is comprised of an assortment of titanium alloy (Ti-6Al-4V ELI per ASTM F136) and polyetheretherketone (PEEK) Polymer (PEEK OPTIMA® LT1 per ASTM F2026) spacers with height expansion capability that is offered in parallel, lordotic and hyperlordotic configurations. The specific implants used in your case are provided in the table above.

What is the device for?

The FORZA® XP Expandable Spacer System implants are used to help restore the natural curvature of the spine. The expandable interbody spacer is inserted into the lumbar disc space and expanded to fit the patient anatomy. These implants are not intended to be used as a stand-alone device and may be used with supplemental fixation selected by the implanting surgeon.

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

The FORZA® XP Expandable 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 FORZA® XP Expandable Spacer System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft; and supplemental fixation system.

Patients must have undergone a regimen of at least six months of non-operative treatment prior to being treated with the FORZA® XP Expandable 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 FORZA® XP Expandable Spacer System implants are used to help restore the natural curvature of the spine.

Side effects

The side effects could be the following (and is 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.

Risks that can remain despite preventive measures

Refer to Side Effects.

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

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.

Precautions and other measures to be taken by the patient or a health professional

No implant can be expected to withstand the unsupported stresses of full weight bearing, prior to secure bone healing. The size, shape and condition of human bones are also contributing factors to the success of the surgery. Patients with previous surgery at the levels to be treated may have different clinical outcomes compared to those without a previous surgery. It is very important that you follow the recommendations of your physician. By following these instructions, you can increase your chances of a successful result and reduce your risk of injury and/or additional surgery.

The FORZA® XP Expandable 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 FORZA® XP Expandable Spacer System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Regular exams, checks and/or care of the device

It is very important that you follow the recommendations of your physician. By following these instructions, you can increase your chances of a successful result and reduce your risk of injury and/or additional surgery.

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

If the bone doesn't actually fuse together as intended, additional loads are placed on the implant that could lead to its failure. Once this happens, patients may develop either new back pain or recurrent leg symptoms.

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 lifetime of the device is dependent on many factors including but not limited to – time it takes to achieve fusion, activity level of patient, compliance of patient to post-op advise provided by the medical professional, occurrence of traumatic events such as a fall or accident and implant size limitation posed by anatomical restrictions. Precautions needed are discussed in a section above.

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

Refer to section on symptoms.

Materials and substances included in the device

Titanium alloy (Ti-6Al-4V ELI per ASTM F136) and Polyetheretherketone (PEEK) Polymer (PEEK OPTIMA® LT1 per ASTM F2026).

Any residues from production that could put the patient at risk

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

Important note:

Please report any serious problem with the FORZA® XP Expandable Spacer System. You must contact Orthofix Inc and the Therapeutic Goods Administration.

Orthofix Inc

Orthofix Inc., 3451 Plano Parkway, Lewisville, TX 75056, USA, by telephone at 1-214-937-3199 or 1-888-298-5700 or by e-mail at 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.)