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 _____

SKYHAWK® Lateral Plate System

SKYHAWK® Lateral Interbody Fusion System

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the SKYHAWK® Lateral Plate System and SKYHAWK® Lateral Interbody Fusion 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 SKYHAWK Lateral Plate System consists of an assortment of non-sterile, single use, titanium alloy (Ti6Al4V ELI per ASTM F136) rigid plates and bone screws. The SKYHAWK Lateral Interbody Fusion System is comprised of a variety of implants fabricated and manufactured from polyetheretherketone (PEEK) per ASTM F2026 with tantalum markers per ASTM F560. The specific implants used in your case are provided in the table above.

What is the device for?

The SKYHAWK Lateral Plate System is intended to be used in skeletally mature patients and is intended to provide immobilization and stabilization of spinal segments. The SKYHAWK Lateral Interbody System is used to help restore the natural curvature of the spine and houses the graft material that aids in the fusion.

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

The SKYHAWK Lateral Plate System is intended to be used in skeletally mature patients in the treatment of the following acute and chronic instabilities of the thoracic and lumbar spine. It may be used from levels T1 to L5 with the following indications:

1. Degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies).

2. Spondylolisthesis.

3. Spinal stenosis.

4. Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis).

5. Tumor.

6. Pseudoarthrosis.

7. Failed previous fusion.

8. Trauma (i.e., fracture or dislocation).

When used as an intervertebral body fusion device, the SKYHAWK Lateral Interbody Fusion System is indicated for use 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

The SKYHAWK Lateral Plate System is intended to be used to provide immobilization and stabilization of spinal segments.

The SKYHAWK Lateral Interbody Fusion System is used as an intervertebral body fusion device.

Side effects

Potential adverse events for the SKYHAWK Lateral Plate System include, but are not limited to:

1. Early or late loosening of any or all of the components.

2. Disassembly, bending, and/or breakage of any or all of the components.

3. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease.

4. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.

5. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.

6. Infection.

7. Vertebral body fracture at, above, or below the level of surgery.

8. Loss of neurological function, including paralysis (complete or incomplete).

9. Non-union, delayed union.

10. Pain, discomfort, or abnormal sensations due to the presence of the device.

11. Hemorrhage.

12. Cessation of any potential growth of the operated portion of the spine.

13. Death.

Note: Additional surgery may be necessary to correct some of these anticipated adverse events

Potential adverse events for the SKYHAWK Lateral Interbody Fusion System 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.

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.

The SKYHAWK Lateral Plate System and the SKYHAWK Lateral Interbody Fusion 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 the SKYHAWK Lateral Plate System and the SKYHAWK Lateral Interbody Fusion System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 SKYHAWK Lateral Plate System and the SKYHAWK Lateral Interbody Fusion 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 the SKYHAWK Lateral Plate System and the SKYHAWK Lateral Interbody Fusion 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), Polyetheretherketone (PEEK) Polymer (PEEK OPTIMA® LT1 per ASTM F2026) and Tantalum per ASTM F560.

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 SKYHAWK Lateral Plate System and the SKYHAWK Lateral Interbody Fusion 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.)