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 _____

Firebird® Spinal Fixation System

(Includes: Firebird® System, Firebird® Deformity System, Firebird® NXG Spinal Fixation System, Phoenix® Minimally Invasive Spinal Fixation System, Phoenix® CDX™ Minimally Invasive Spinal Fixation System, JANUS® Midline Fixation Screw, JANUS® Fenestrated Screw)

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the Firebird® Spinal Fixation 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
Firebird® Spinal Fixation System, consists of a variety of components made of titanium or cobalt chrome alloy that are attached to the vertebral body and ilium by means of screws or hooks to form a construct. The construct may consist of rods, multi-axial and mono-axial pedicle screws, set screws, lateral offsets, bone screws, screw bodies, cross-connectors, hooks and iliac connectors. The specific implants used in your case are provided in the table above.

What is the device for?
The Firebird® Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments, while fusion occurs.

Kind of patient on whom the device is intended to be used
The Firebird® Spinal Fixation System is used to treat patients with instabilities or deformities caused by:

1. Degenerative disc disease (back pain originating from a degenerated/damaged disc).
2. Spondylolisthesis (vertebral bone slips forward onto the vertebral bone below it).
3. Trauma (fracture or dislocation).
4. Spinal stenosis (narrowing of the spinal canal).
5. Deformities or curvatures (scoliosis, kyphosis, lordosis).
6. Tumor.
7. Pseudo arthrosis (failure to fuse), and
8. Failed previous fusion.

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

Intended performance of the device
Constructs made from the Firebird® Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments, while fusion occurs.

Side Effect
The side effects could be the following (and is not limited to):

1. Neurological, vascular or visceral injury.

2. Proximal or distal junctional kyphosis.

3. Pancreatitis.

4. Device failure, such as screw or rod bending, breakage, disassembly or loosening. Pediatric patients may be at increased risk for device-related injury because of their smaller stature.

5. Loss of fixation.

6. Non-union.

7. Fracture of the vertebra.

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

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

10. Change in spinal curvature, loss of correction, height, and/or reduction.

11. Infection.

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

13. Hemorrhage.

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

15. Death.

16. The JANUS Fenestrated Screw when used with KYPHON HV-R Fenestrated Screw Cement may include adverse events of hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.

17. The JANUS Fenestrated Screw when used with KYPHON HV-R Fenestrated Screw Cement may include serious adverse events, some with fatal outcomes, associated with the use of acrylic bone cements in the spine include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and cardiac embolism. Although the majority of these adverse events present early with the post-operative period, there have been some reports of diagnoses beyond a year or more after the procedure.

18. The JANUS Fenestrated Screw when used with KYPHON HV-R Fenestrated Screw Cement may include other reported adverse events for acrylic bone cements intended for use in the spine including leakage of the bone cement beyond the site of its intended application with introduction into the vascular system resulting in, but not limited to, embolism of the lung and/or heart or other clinical sequelae.

Risk that can remain despite preventive measure
Refer to Side Effects.

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

1. The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw mal-positioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.
2. The safety and effectiveness of pedicle screw systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. The safety and effectiveness of these devices for any other condition are unknown.
3. The benefit of spinal fusion utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
4. Potential risks identified with the use of this device system which may require additional surgery include: device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury and vascular or visceral injury.
5. Failure to achieve arthrodesis will result in eventual loosening and failure of the device.
6. The Systems have not been evaluated for safety and compatibility in the MR environment.
7. The JANUS Fenestrated Screw when used with KYPHON HV-R Fenestrated Screw Cement may include the potential for cement leakage which may cause tissue damage, nerve or circulatory problems, and other serious adverse events. These risks may increase with the number of spinal levels where bone cement is utilized, and also with the volume of bone cement used.

Adverse patient reactions affecting the cardiovascular system, including Bone Cement Implantation Syndrome (BCIS), have been associated with the use of bone cements. Hypotensive reactions have occurred between 10 and 165 seconds following application of bone cement and have lasted from 30 seconds to 5 or more minutes. Some have progressed to cardiac arrest.

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

The Firebird® Spinal Fixation System implants have been shown to be valuable aids to surgeons in the treatment of bony fusions. These devices do not have the capabilities of living bone. Intact living bone is self-repairing, flexible and occasionally breaks and/or degrades. The anatomy of the human body places a size limitation on any artificial fixation device used in surgery. The maximum size limitation increases the chances of the mechanical complications of loosening, bending or breaking of the devices. Any of these complications could result in the need for additional surgery. Accordingly, it is very important that you follow the recommendations of your physician. Use braces as instructed. By following these instructions, you can increase your chances of a successful result and reduce your risk of injury and/or additional surgery.

The Systems have not been evaluated for safety and compatibility in the MR environment.

Regular Exams, check and/or care of the device

It is very important that you follow the recommendations of your physician. Use braces as instructed. 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, the screws and rods will predictably work themselves loose over time, or even break. Once this happens, patients may develop either new back pain or recurrent leg symptoms.

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 Firebird® Spinal Fixation System is a temporary internal fixation device. 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 (per ASTM F136) and Cobalt Chrome alloy (per ASTM F1537).

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 Firebird® Spinal Fixation System. You must contact Orthofix Inc and the Therapeutic Goods Administration.

Orthofix
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.)