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 _____

Spinal Fixation System

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the 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

The Spinal Fixation System is a temporary, titanium alloy, multiple component system comprised of a variety of non-sterile, single use components that allow the surgeon to build a spinal implant construct. The construct may consist of screws, hooks, rods, spacers, staples, washers, dominos, lateral offsets, and cross-connectors. The specific implants used in your case are provided in the table above.

What is the device for?

The Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments.

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

The Spinal Fixation System, when used for pedicle screw fixation, is intended only for patients:

1. Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint.

2. Who are receiving fusion using autogenous bone graft only.

3. Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below).

4. Who are having the device removed after the development of a solid fusion mass.

The Spinal Fixation System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine:

1. Degenerative spondylolistheses with objective evidence of neurologic impairment.

2. Fracture.

3. Dislocation.

4. Scoliosis.

5. Kyphosis.

6. Spinal tumor.

7. Failed previous fusion (pseudoarthrosis)

The Spinal Fixation System, when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following indications:

1. Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by 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).

The Spinal Fixation System, when used for posterior non-pedicle screw fixation system of the non-cervical spine, is intended for the following indications:

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

2. Spondylolistheses.

3. Spinal stenosis.

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

5. Tumor.

6. Pseudoarthrosis.

7. Failed previous fusion.

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

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 Spinal Fixation System is intended to provide immobilization and stabilization of spinal segments, while fusion occurs. The primary goal of this surgery is to arthrodese selected vertebrae.

Side effects

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

1. Device component fracture.

2. Loss of fixation.

3. Non-union.

4. Fracture of the vertebra.

5. Neurological injury.

6. Vascular or visceral injury.

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

8. Disassembly and/or bending of any or all of the components.

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

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

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

12. Infection.

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

14. Hemorrhage.

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

16. Death.

Note: Potential risks identified with the use of the device system may require additional surgery..

Risks that can remain despite preventive measures

Refer to Side Effects.

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

1. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
2. 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.
3. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
4. The Spinal Fixation 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 Spinal Fixation 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

Physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation device. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components. To allow the maximum potential for a successful surgical result, the patient or device should not be exposed to mechanical vibration that may loosen the device construct. Accordingly, 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 Spinal Fixation 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 Spinal Fixation 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, 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 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

These implants are temporary internal fixation devices. Internal fixation devices are designed to assist in the stabilization of the operative site during normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. In most cases removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, complication may occur as follows:

a. Corrosion, with localized tissue reaction or pain.

b. Migration of implant position resulting in injury.

c. Risk of injury from postoperative trauma.

d. Bending, loosening and/or breakage, which could make removal impractical or difficult.

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

f. Possible increased risk of infection.

g. Bone loss caused by stress shielding.

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).

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 Spinal Fixation 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.)