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 _____

Unity® Lumbosacral Fixation System

Spinal Fixation System

Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the Unity® Lumbosacral 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

Unity® Lumbosacral Fixation System.

The Unity Lumbosacral Fixation System is a supplemental fixation construct that consists of two implantable titanium alloy plates – the Unity LX Lumbar Fixation Plate and the Unity 51 Lumbosacral Fixation Plate – and screws that are provided non-sterile.

What is the device for?

The Unity Lumbosacral Fixation System devices used in your recent spinal surgery are metallic implants that attach to the bone and aid in the healing of bone grafts until a solid spinal fusion develops.

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

The Orthofix Unity 51 Lumbosacral Fixation Plate is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral (L5-S1) level below the bifurcation of the vascular structures. The Orthofix Unity LX Lumbar Fixation Plate is indicated for use as an anteriorly or anterolaterally placed supplemental fixation device for the lumbar region of the spine above the bifurcation of the vascular structures. When properly used, this system will help provide temporary stabilization until a solid spinal fusion develops. Specific indications include:

1. Degenerative disc disease (defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies).
2. Pseudoarthrosis.
3. Spondylolysis.
4. Spondylolisthesis.
5. Fracture.
6. Neoplastic disease.
7. Unsuccessful previous fusion surgery.
8. Lordotic deformities of the spine.
9. Idiopathic thoracolumbar or lumbar scoliosis.
10. Deformities (i.e., scoliosis, kyphosis, and/or lordosis) associated with deficient posterior elements such as that resulting from laminectomy, spina bifida, or myelomenigocele.

11. Neuromuscular deformity (i.e., scoliosis, lordosis, and/or kyphosis) associated with pelvic obliquity.

Special operating instructions for the use of the device

There are no special operating instructions for the patient.

Intended performance of the device

The Orthofix Unity 51 Lumbosacral Fixation Plate is indicated for use as an anteriorly placed supplemental fixation device for the lumbosacral (L5-S1) level below the bifurcation of the vascular structures. The Orthofix Unity LX Lumbar Fixation Plate is indicated for use as an anteriorly or anterolaterally placed supplemental fixation device for the lumbar region of the spine above the bifurcation of the vascular structures. When properly used, this system will help provide temporary stabilization until a solid spinal fusion develops.

Side Effects

Potential adverse events 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 and 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.

Risks that can remain despite preventive measures

Refer to Side Effects.

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

The Unity Lumbosacral Fixation System is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.

Safety information regarding MRI (Magnetic Resonance Imaging):

The Unity Lumbosacral 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 the Unity Lumbosacral 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

The temporary internal fixation devices used in your recent spinal surgery are metallic implants that attach to the bone and aid in the healing of bone grafts. These 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.

To achieve maximum results, the patient should not be exposed to excessive mechanical vibrations. The patient should not smoke or consume alcohol during the healing process.

If a non-union develops or if the components loosen, the devices should be revised or removed before serious injury occurs. Failure to immobilize the non-union, or a delay in such, will result in excessive and repeated stresses on the implant. It is important that immobilization of the spinal segment be maintained until fusion has occurred.

Regular exams, checks and/or care of the device

The requirement for routine follow-up after implantation is determined by your primary surgeon. 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.

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

Some symptoms may indicate that the device is not functioning as it should. These include, but are not limited to: early or late loosening of any or all of the components, disassembly, bending, and/or breakage of any or all the components, pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain, post-operative change in spinal curvature, loss of correction, height, and/or reduction, infection, vertebral body fracture at, above, or below the level of surgery, loss of neurological function, including paralysis (complete or incomplete), non-union or delayed union, Pain, discomfort, or abnormal sensations due to the presence of the device, and cessation of any potential growth of the operated portion of the spine.

These symptoms and any other adverse or unexpected effects should be reported to your primary surgeon for assessment.

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 the normal healing process. The duration of treatment required is dependent on a variety of factors, and should be determined by your primary surgeon. Adherence to the instructions provided in the section titled, "Precautions and other measures to be taken by the patient or a health professional" will increase the likelihood of successful results and reduce your risk of injury and/or the need for additional surgery. 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.

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

Refer to Symptoms

Materials and substances included in the device

Unity Lumbosacral Fixation System implants are made of 6AL-4V ELI Titanium Alloy per ASTM F136.

Any residues from production that could put the patient at risk

Unity Lumbosacral Fixation System 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 Unity Lumbosacral Fixation 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 Unity Lumbosacral Fixation System. You must contact Orthofix and the Therapeutic Goods Administration.

Orthofix

3451 Plano Parkway, Lewisville, TX 75056, USA
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.)