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 _____

# Connector System

## Patient Information Leaflet

Dear Patient,

During your surgery, the devices referenced above from the Connector 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 Connector System includes a variety of non-sterile implants manufactured from Titanium alloy comprised of bypass connectors, rod to rod connectors, Z rods, and an axial in-line connector with an attached rod. The specific implants used in your case are provided in the table above.

**What is the device for?**

The Connector System is designed to reduce the complexity of revising and extending existing constructs from the Occiput to the Ilium. The Connector System implant options offered eliminate the need to remove existing hardware while providing stability to adjacent levels.

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

When used with the Centurion POCT System or Ascent POCT System for Posterior Occipital-Cervical-Thoracic (Occ – T3):

The Connector System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the craniocervical junction, the cervical spine (C1 to C7) and the thoracic spine (T1 – T3): traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (e.g. pseudoarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The Connector System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion.

When used with the Firebird Spinal Fixation System/Phoenix MIS Spinal Fixation System or Spinal Fixation System (SFS) for Thoracic, Lumbar, and Sacral Spine Fixation (T1-S2/Ilium):

The Connector System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion as a pedicle screw fixation system (T1-S2/Ilium), or as an anterolateral fixation system (T8-L5), in the treatment of the following acute and chronic instabilities or deformities:

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

2. Spondylolisthesis,

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

4. Spinal stenosis,

5. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),

6. Tumor,

7. Pseudoarthrosis, and

8. Failed previous fusion

When used for posterior pedicle screw fixation in pediatric patients, the Connector System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach. The Connector System is intended to be used with autograft or allograft.

**Special operating instructions for the use of the device**

There are no special operating instructions for the patient.

**Intended performance of the device**

The Connector System is designed to reduce the complexity of revising and extending existing constructs from the Occiput to the Ilium. The Connector System implant options offered eliminate the need to remove existing hardware while providing stability to adjacent levels.

**Side effects**

Potential adverse events include, but are not limited to:

1. Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy)

2. Proximal or distal junctional kyphosis

3. Pancreatitis

4. Pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients, and pediatric patients may be at increased risk for device-related injury because of their smaller stature.

5. Device component fracture

6. Loss of fixation

7. Non-union

8. Fracture of the vertebra

9. Neurological injury

10. Vascular or visceral injury

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

12. Disassembly and/or bending of any or all components

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

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

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

16. Infection

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

18. Hemorrhage

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

20. Death

Note: 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.

**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. Adverse effects related to pedicle screw fixation, such as rod bending, breakage, or loosening, may also occur in pediatric patients. Pediatric patients may be at increased risk for device-related injury because of their small stature.
5. The Connector 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 Connector 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 changes of the mechanical complication of loosening, bend, or breaking of 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 Connector 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 Connector 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. 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 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 Connector 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).

**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 Connector 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.)