INSTRUCTIONS FOR USE

Important Information – Please Read Prior to Use

Rx Only

CE 2797

Orthofix US LLC
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Australian Sponsor
Emergo Australia
Level 20, Tower II
Darling Park
201 Sussex Street
Sydney, NSW 2000
Australia

EU REP Medical Device Safety Service
(MDSS)
Schiffgraben 41
30175 Hannover
Germany
www.mdss.com

Device System Name:

Firebird® Spinal Fixation System

which 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

English EN **2-3**

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Description:

The Firebird Spinal Fixation Systems include temporary, multiple component systems comprised of a variety of non-sterile and sterile single use components made of titanium alloy or cobalt chrome alloy that allow the surgeon to build a spinal implant construct. The systems are attached to the vertebral body and ilium by means of screw or hook fixation to the non-cervical spine. The systems consist of an assortment of rods, multi-axial and mono-axial pedicle screws, set screws, lateral offsets, bone screws, screw bodies, hooks, iliac connectors and sterile packed HA coated bone screws.

A subset of the systems' components may be used in pediatric patients. These components consist of a variety of screws ranging in diameters from 4.0mm to 7.5mm and lengths ranging from 25mm to 60mm.

Indications for Use (US, AE, PR):

The Firebird Spinal Fixation Systems are 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), 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.
8. Failed previous fusion.

When used for fixation to the ilium, the offset connectors of the Firebird Spinal Fixation System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

The Firebird Spinal Fixation Systems components are used with certain components of the Spinal Fixation System (SFS), including rods, rod connectors and cross-connectors.

When used for posterior pedicle screw fixation in pediatric patients, the Firebird Spinal Fixation Systems are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach.

The Firebird Spinal Fixation Systems are intended to be used with autograft or allograft.

The Phoenix MIS Fixation System when used with the Firebird Spinal Fixation Systems is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

The JANUS Midline Fixation Screw and the JANUS Fenestrated Screw when used with the Firebird Spinal Fixation Systems is indicated to provide the surgeon with an open, minimally invasive or midline approach for posterior spinal surgery. The JANUS Fenestrated Screws are intended to be used with saline and radiopaque dye.

Indications for Use (All Other Regions):

The Firebird Spinal Fixation Systems are 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), 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).

When used for fixation to the ilium, the offset connectors of the Firebird Spinal Fixation System must be used in conjunction with pedicle screws placed at the S1 or S2 spinal level.

The Firebird Spinal Fixation Systems components are used with certain components of the Spinal Fixation System (SFS), including rods, rod connectors and cross-connectors.

When used for posterior pedicle screw fixation in pediatric patients, the Firebird Spinal Fixation Systems are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. Pediatric pedicle screw fixation is limited to a posterior approach.

The Firebird Spinal Fixation Systems are intended to be used with autograft or allograft.

The Phoenix MIS Fixation System when used with the Firebird Spinal Fixation Systems is indicated to provide the surgeon with a minimally invasive approach for posterior spinal surgery.

The JANUS Midline Fixation Screw and the JANUS Fenestrated Screw when used with the Firebird Spinal Fixation Systems is indicated to provide the surgeon with an open, minimally invasive or midline approach for posterior spinal surgery. The JANUS Fenestrated Screws are intended to be used with saline and radiopaque dye.

Contraindications:

Contraindications include, but are not limited to:

1. Morbid obesity.
2. Mental Illness.
3. Alcoholism or drug abuse.
4. Pregnancy.
5. Metal sensitivity/allergies.
6. Severe osteopenia.
7. Patients unwilling or unable to follow post-operative care instructions.
8. Use of the Firebird offset connectors for fixation to the ilium is contraindicated when the sacrum is absent or insufficient for implantation of pedicle screws at the S1 or S2 spinal level.
9. Any circumstances not listed under the heading indications.

Potential Adverse Events:

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. Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy).
2. Pedicle screw malpositioning, with or without neurological or vascular injury.
3. Proximal or distal junctional kyphosis.
4. Pancreatitis.
5. Pedicle screw failure, 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.
6. Device component fracture.
7. Loss of fixation.
8. Non-union.
9. Fracture of the vertebra.
10. Neurological injury.
11. Vascular or visceral injury.
12. Early or late loosening of any or all of the components.
13. Disassembly and/or bending of any or all components.
14. Foreign body (allergic) reaction to implants, debris, corrosion products, and graft material, including metallosis, straining, tumor formation, and/or auto-immune disease.
15. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.
16. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
17. Infection.
18. Pain, discomfort, or abnormal sensations due to the presence of the device.
19. Hemorrhage.
20. Cessation of any potential growth of the operated portion of the spine.
21. Death.

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

Warnings and Precautions:

1. The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.
2. 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 malpositioning 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.
3. The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient.
4. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection of placement of the implants are important considerations in the successful utilization of the system in pediatric patients.
5. The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.
6. 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. These conditions are: significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other condition are unknown.
7. The benefit of spinal fusion utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
8. 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.
9. Single use only. Reuse of devices labeled as single-use (e.g. implants, drills, tacks, trial rods) could result in injury or reoperation due to breakage or infection.
10. Non-sterile; the screws, hooks, rods, dominoes, lateral offsets, spacers, staples, washers, locking nuts, cross connectors, and instruments are sold non-sterile and therefore must be sterilized before use.
11. To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used.
12. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
13. Excessive torque applied to the screws may strip the threads in the bone.
14. All implants are intended for SINGLE USE ONLY. Any used implant should be discarded. Even though the device may appear undamaged, it may have small defects and internal stress patterns that may lead to fatigue failure.
15. The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
16. Based on fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
17. Mixing of dissimilar metals can accelerate the corrosion process. Do not use the titanium alloy or cobalt chrome alloy components of this system with implants of other material composition or components from different manufacturers unless specifically stated.
18. The Firebird Spinal Fixation System and Phoenix MIS Fixation System have not been evaluated for safety and compatibility in the MR environment, nor have the Firebird Spinal Fixation System or the Phoenix MIS Fixation System been tested for heating or migration in the MR environment.
19. Do not attempt to re-sterilize single-use implants that come in contact with body fluids.
20. When using the offset connectors to connect the Firebird spinal construct to the ilium, pedicle screws must be used at the S1 or S2 level of the spine. Do not use the offset connectors to connect the ilium without this intermediate screw fixation.
21. The safety, efficacy and performance of the system have been established for conditions in which the system is used as intended and when used as identified in the Indications for Use. Performance of the system has not been evaluated for use that is contrary to the Intended Use, Indications for Use or for use that is contraindicated. Failure to use the system as indicated could detrimentally affect the performance of its components.
22. Other adverse effects related to pedicle screw fixation, such as screw or 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.
23. The correct handling of the implant is extremely important. Implants should not be excessively or repeatedly bent, notched or scratched. These operations can produce defects in surface finish and internal stress concentrations, which may become the focal point for eventual failure of the device.
24. HA coated screws are provided STERILE. Do not use if the package is opened or damaged or if the expiration date has passed.
25. DO NOT re-sterilize the HA coated screws as this could result in injury or require reoperation due to breakage.
26. The safety and effectiveness of this device has not been established when used in conjunction with bone cement or for use in patients with poor bone quality (e.g., osteoporosis, osteopenia). This device is intended only to be used with saline or radiopaque dye.

MRI Compatibility Information:

Non-clinical testing and MRI simulations that included in-vivo, clinically relevant modeling were performed to evaluate the entire family of the Pedicle Screw System. Non-clinical testing demonstrated that the entire family of the system is MR Conditional. A patient with an implant from this family can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla or 3-Tesla, only
- Maximum spatial gradient magnetic field of 4,000-gauss/cm (40-T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, an implant from the Pedicle Screw System is expected to produce a maximum temperature rise of 3.0°C after 15 minutes of continuous scanning (i.e., per pulse sequence).

In non-clinical testing, the image artifact caused by an implant from the Pedicle Screw System extends approximately 8-mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

Cleaning and Disinfection:

The HA coated screw implants are sterilized using gamma radiation sterilization. Do not re-sterilize. All other system implants are provided clean but not sterile. Once an implant comes in contact with any human tissue or bodily fluid it should not be re-sterilized or used. Please discard all contaminated implants.

Please refer to AW-10125289, Non-Sterile Surgical Instruments and Implants Reprocessing Guide, for instruction on the cleaning and disinfection of surgical instruments.

Sterilization:

The System HA coated screw implants are sterilized using gamma radiation sterilization. Do not re-sterilize. All other implants and instruments are supplied NON-STERILE.

Please refer to AW-10125289, Non-Sterile Surgical Instruments and Implants Reprocessing Guide, for instruction on the sterilization of implants, components, and instrumentation.

Patient Information:

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.

Packaging:

Packages for each of the components should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage prior to use. Damaged packages or products should not be used and should be returned to Orthofix.

The System instruments and implants are provided in a modular case specifically intended to contain and organize the system components. The system instruments are organized into trays within the modular case for easy retrieval during surgery. These trays also provide protection to the system components during shipping. Additionally, individual instruments and implants will be provided in sealed poly bags with individual product labels attached to them.

Note: The HA coated screws are provided sterile. Do not use if the package is opened or damaged, or if the expiration date has passed.

Product Complaints:

Any Health Care Professional (e.g., customer or user of this system of products) who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Orthofix US LLC, 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.

Further Information:

Recommended operative techniques for the use of these systems are available upon request from Orthofix at the phone numbers provided above.

Latex Information:

The implants, instruments and/or packaging material for the System are not formulated with and do not contain natural rubber. The term "natural rubber" includes natural rubber latex, dry natural rubber, and synthetic latex or synthetic rubber that contains natural rubber in its formulation.

Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

R_X Only	Federal (U.S.A.) law restricts this device to sale by or on the order of a physician		
	See Instructions for Use		Use By Date
	Orthofix.com/IFU		Manufacturer
2	Single Use Only Do Not Reuse	EU REP	Authorized Representative
REF	Catalogue Number	2 STERILIZE	Do Not Resterilize
NON STERILE	Provided Non-Sterile	SN	Serial Number
STERILE	Sterilized Using Irradiation	LOT	Lot Number
MR	MR Conditional		

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