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
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

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 screws 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 7.3mm and lengths ranging from 25mm to 60mm.

Indications for Use:
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).
5. Deformities or curves (i.e., scoliosis, kyphosis, and/or lordosis).
6. Tumor.
7. Pseudarthrosis.
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 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.
5. Metal sensitivity/allergies.
6. Severe osteoporosis.
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 anatomical 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.
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.
20. Cessation of any potential growth of the operated portion of the spine.

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
Within the system, certain screw types require disassembly prior to cleaning. The following instruments are recommended: Screw Driver (36-1832) and the Midline Modular Screw Driver (36-1833). No other instruments are specified for this purpose.

**For All Other Firebird System Cases and Caddies:**

- Caution should be exercised when handling these instruments. Improper use or handling may lead to damage and possible improper operation.
- Cleaning of these instruments can include the use of neutral cleaners followed by a deionized water rinse. All products should be tested for compatibility with the specific system.
- Sterilize. All other system implants are provided clean but not sterile. Once an implant comes into contact with body fluids, it should be treated with care.
- If visible soil is noted, the cleaning process should be repeated until no visible soil is noted.
- 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.
- To facilitate cleaning, a sufficient quantity of autologous bone or other appropriate material should be used. Failure to achieve an adequate cleaning result will lead to eventual loosening and failure of the device.
- Excessive torque applied to the screws may strip the threads in the bone.
- DO NOT REUSE IMPLANTS. Discard used, damaged, or otherwise suspect implants.
- Sterilize. All instruments with moving parts (e.g., knobs, triggers, hinges) should be placed in the instrument washer/disinfector basket and processed through a standard instrument washer/disinfector cleaning cycle.
- A 10-minute cycle with standard steam or dry heat processes is adequate for sterilization. Use of recommended temperatures is important for optimal performance of enzymatic detergents.
- Manual Cleaning:
  1. Completely submerge instruments in an enzymatic detergent and allow to soak for 30 minutes.
  2. For optimal results, instruments should be cleaned within 30 minutes of use or after removal from solution to minimize the potential for drying prior to cleaning.
  3. Thoroughly and aggressively flush lumens, holes and other difficult to clean areas. Lumens should be cleaned with a long, narrow, soft nylon bristle brush or a pipe cleaner brush.
  4. Enzymatic detergent should be used for manual and automated cleaning. All enzymatic detergents should be prepared at the use concentration and temperature recommended by the manufacturer.

**MRI Compatibility Information:**

- The MR compatibility of this 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 systems in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

**Cleaning:**

- 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.
- Discard all contaminated implants.

**For Firebird Spinal Fixation System Cases**

- For Firebird Spinal Fixation System Cases 44-9010, 44-9011, 44-9012, 44-9013, 44-9020, 44-9030, 44-9040, 44-9560 and 61-9060:

  **Automated Cleaning:**
  1. Completely submerge the instruments in an enzymatic detergent and allow to soak for at least 2 minutes. Use a soft nylon bristle brush to gently scrub the device until all visible soil has been removed. Particular attention must be given to crevices, lumens, mated surfaces, connectors and other hard-to-clean areas. Lumens should be cleaned with a long, narrow, soft nylon bristle brush or a pipe cleaner brush.
  2. Remove the instruments from the enzymatic detergent and rinse in tap water for a minimum of 3 minutes. Thoroughly and aggressively, flush lumens, holes and other difficult to reach areas.
  3. Place prepared cleaning solution in a sonication unit. Completely submerge device in cleaning solution and sonicate for 10 minutes.
  4. Rinse instrument in purified water for at least 2 minutes or until there is no sign of blood or soil on the device or in the rinse stream. Thoroughly and aggressively, flush lumens, holes and other difficult to reach areas.
  5. Repeat the sonication and rinse steps above.
  6. Remove excess moisture from the instrument with a clean, absorbent and non-shedding wipe.
  7. Inspect the instruments for visible soil.
  8. If visible soil is noted, repeat the steps listed above.

- Sterilization of the HA coated screw implants are sterilized using gamma radiation sterilization. Do not re-sterilize. All other implants and instruments are supplied NON-STERILE.
For Firebird Spinal Fixation System Cases 44-9010, 44-9011, 44-9012, 44-9013, 44-9020, 44-9030, 44-9040, 44-9050 and 61-9060:
The Firebird Spinal Fixation System should be sterilized by the hospital using one of the following recommended cycles when utilizing an FDA cleared sterilization wrap:

<table>
<thead>
<tr>
<th>Method</th>
<th>Temperature</th>
<th>Exposure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>250°F (121°C)</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>270°F (132°C)</td>
<td>8 minutes</td>
</tr>
</tbody>
</table>

For All Other Firebird System Cases and Caddies:
Prior to use, all implants and instruments should be placed in the appropriate Orthofix case which will be wrapped in an FDA cleared sterilization wrap, or individually wrapped, and placed in the autoclave for sterilization by the hospital using one of the following recommended cycles:

<table>
<thead>
<tr>
<th>Method</th>
<th>Temperature</th>
<th>Exposure time</th>
<th>Drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>270°F (132°C)</td>
<td>4 minutes</td>
<td>30 minutes</td>
</tr>
<tr>
<td>Steam</td>
<td>270°F (132°C)</td>
<td>30 minutes</td>
<td>Double wrapped</td>
</tr>
</tbody>
</table>

Firebird NXG, JANUS Midline Fixation Screw and JANUS Fenestrated Screw
Sterilization in Rigid Sterilization Containers:
When using rigid sterilization containers, clean, inspect and prepare the rigid sterilization container according to the manufacturer’s instructions.

Select the appropriate rigid sterilization container with either filtered bottom or solid bottom to properly enclose the Orthofix case(s) (recommended 23¼” long x 11¼” wide container). The following sterilization cycle has been validated:

- Sterilization Method: Steam
- Cycle: Prevac
- Temperature: 270°F (132°C)
- Preconditioning: Per manufacturer’s settings
- Exposure time: 4 minutes
- Drying time: 30 minutes

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 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.

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.