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

Click directory below for desired language

English  EN  2-4
The JANUS® Midline Fixation Screw and the JANUS® Fenestrated Screw, when used with the Firebird Spinal Fixation Systems, are intended to provide the surgeon with an open, minimally invasive or midline approach for posterior spinal surgery.

The JANUS Fenestrated Screw with Cement when used in conjunction with Medtronic KYPHON® HV-R Fenestrated Screw Cement, the JANUS Fenestrated Screws are 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 thoracic and lumbar spine in whom life expectancy is of insufficient duration to permit achievement of fusion. The JANUS Fenestrated Screws augmented with Medtronic KYPHON HV-R Fenestrated Screw Cement are for use at spinal levels where the structural integrity of the spine is not severely compromised. The JANUS Fenestrated Screw with Cement when used in conjunction with Medtronic KYPHON HV-R Fenestrated Screw Cement is further indicated to include Diminished bone quality (i.e., osteoporosis, osteopenia, metastatic disease).

**Contraindications:**
Contraindications include, but are not limited to:
1. Morbid obesity.
2. Mental Illness.
3. Alcoholism or drug abuse.
5. Metal, bone cement and Hydroxyapatite (HA) coating sensitivity/allergies.
6. Hydroxyapatite (HA) coated screws are not to be used with bone cement.
7. Severe osteopenia.
8. Patients unwilling or unable to follow post-operative care instructions.
9. 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.
10. Any circumstances not listed under the Indications for Use section.

**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.
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, bone cement, 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.
22. The JANUS Fenestrated Screw when used with KYPhON HV-R Fenestrated Screw Cement may include serious adverse events, some with fatal outcomes, associated with the use of acrylic bone cements in the spine include myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and cardiac embolism. Although the majority of these adverse events present early with the post-operative period, there have been some reports of diagnoses beyond a year or more after the procedure.
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 if 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 under age 10 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 selection of pedicle screw fixation 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 bone cement for 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 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 (pseudarthrosis). 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.

10. Non-sterile; the screws, hooks, rods, dominoes, lateral offsets, spacers, staples, washers, locking nuts, cross connectors, and instruments are sold non-sterile and 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. DO NOT REUSE IMPLANTS. Discard used, damaged, or otherwise suspect implants.

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 compatibility 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 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 and implantation 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 sterilized. 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 JANUS Fenestrated Screw when used with KYPHON HV-R Fenestrated Screw Cement, refer to the Medtronic HV-R Fenestrated Screw Cement instructions for use for additional information, contraindications, warnings, precautions and cement preparation instructions.

27. The JANUS Fenestrated Screw when used with KYPHON HV-R Fenestrated Screw Cement can include the potential for cement leakage which may cause tissue damage, nerve or circulatory problems, and other serious adverse events. These risks may increase with the number of spinal levels where cement is utilized, and also with the bone cement used.

28. The JANUS Fenestrated Screw when used with KYPHON HV-R Fenestrated Screw Cement, monitor patients carefully for any change in blood pressure during and immediately following the application of bone cement. Adverse patient reactions affecting the cardiovascular system, including Bone Cement Implantation Syndrome (BCIS), have been associated with the use of bone cements. Hypo- or hypotensive reactions have occurred between 15 and 165 seconds following application of bone cement and have lasted from 30 seconds to 5 or more minutes. Some have progressed to cardiac arrest. Patients should be monitored carefully for any change in blood pressure during and immediately following the application of bone cement, especially those potentially at increased risk for peri-operative death, including elderly patients, patients with underlying cardiac or pulmonary compromise, and patients being treated for multiple vertebral body fractures in one procedure.

29. The JANUS Fenestrated screws when used with the Medtronic KYPHON HV-R Fenestrated Screw Cement should NOT be placed bicortically. It is important not to breach the pedicle wall or anterior cortex of the vertebral body to avoid cement extrusion into the retrospinal space.

MRI Compatibility Information:
The systems have 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. Please discard all contaminated implants.

For Firebird Spinal Fixation System Cases 44-9011, 44-9012, 44-9013, 44-9020, 44-9030, 44-9040, 44-9050 and 61-9060:
All instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Cleaning can impact the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

For All Other Firebird System Cases and Caddies:
All instruments must be thoroughly cleaned after each use. Cleaning may be done using validated hospital methods or following the validated cleaning processes described below.

From Point of Use:
Whenever possible, do not allow blood, debris or body fluids to dry on instruments. For best results and to prolong the life of the surgical instrument, reprocess immediately after use.

Instructions for Disassembly and Assembly:
Prior to cleaning please see the operative technique for disassembly and assembly instructions for the five instruments which require disassembly prior to cleaning, the: Multi-Axial Screw Driver (20-0200), Mono-Axial Screw Driver (20-0300), Multi-Axial Screw Driver (36-1831), Modular Screw Driver (36-1832) and the Midline Modular Screw Driver (36-1833). No other instruments within the system require disassembly prior to cleaning.

Preparation for Cleaning:
1. Any instruments with moving parts (i.e., knobs, triggers, hinges) should be separated and placed in the open position to allow better access of the cleaning fluid to the difficult to clean areas. Use a soft cloth or plastic bristle brush to remove any visible soil from the outside and inside of the instruments.

2. Soak the instruments for a minimum of 10 minutes in sterile water prior to the manual or automated cleaning process.

3. Use a soft cloth or a soft plastic bristle brush to remove any visible soil from the outside and inside of the instruments.

4. Manually agitate instruments in Vesphene® solution for 15 minutes.

5. Allow the instruments to sit for 30 minutes.

6. Rinse the instruments in USP <1231> purified water for 1.5 minutes.

7. Hang dry the device.

8. Plastic bristle brush or pipe cleaner long enough to reach the entire length of the interior lumen to remove any visible soil from the outside and inside of the instruments.

9. From Point of Use:
When necessary to clean instruments for reuse, please see the following cleaning process.

Automated Cleaning:
1. After disassembly of the instruments, use a soft cloth and/or a soft plastic bristle brush to remove any visible soil from the outside and inside of the instrument.

2. Prepare Vesphene® isoeugenol at the use-dilution recommended on the label directions (1 ounce per gallon) as follows: Add 1 ml of Vesphene® isoeugenol to 128.0 ml of potable tap water per the manufacturer’s recommendations.

3. Bathe instruments in prepared room temperature solution as recommended by the detergent manufacturer.

4. Manually agitate instruments in Vesphene® solution for 15 minutes.

5. Scrub instruments with a soft plastic bristle brush if visible soil is noted and use a soft plastic bristle brush or pipe cleaner long enough to reach the entire length of the interior lumen to remove the soil.

6. Rinse the instruments in USP <1231> purified water for 1.5 minutes.

7. Hang dry the device.

8. Visually inspect the instruments for visible soil.

9. If visible soil is noted, repeat the steps listed above.
5. The following automated cleaning cycle is recommended (minimum recommended times are provided for each stage):
   a. Pre-Wash 1: cold potable water, 2 minutes
   b. Enzyme/Detergent treatment:
      1. Spray, 20 seconds
      2. Soak, 1 minute
      3. Rinse cold potable water, 15 seconds
      4. Rinse cold potable water, 15 seconds
      c. Wash @ 65°C, 2 minutes using Endozime AW Plus®
   d. Rinse 1: hot potable water, 15 seconds
   e. Rinse 2: hot potable water, 15 seconds
   f. Rinse 3: hot potable water, 15 seconds
   g. Rinse 4: hot potable water, 15 seconds
   h. Thermal rinse @ 93°C for 1 minute
   i. Heated USP Purified Water Rinse 1: re-circulating 10 seconds
   j. Heated USP Purified Water Rinse 2: non re-circulating 10 seconds
   k. Drying: 7 minutes, 115°C
   l. Visually inspect the instruments for visible soil.
   m. If visible soil is noted, repeat the above listed steps until no visible soil is noted.

Note: Certain cleaning solutions such as those containing caustic soda, formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage instruments. These solutions should not be used.

Note: Visually inspect instruments after cleaning and prior to each use. Discard or return to Orthofix any instruments that are broken, discolored, corroded, have cracked components, pits, gouges, or are otherwise found defective. Do not use defective 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-STEREIL.

For Firebird Spinal Fixation System Cases 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>
</tbody>
</table>

For All Other Firebird Systems 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>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>270°F (132°C)</td>
<td>15 minutes</td>
</tr>
</tbody>
</table>

Firebird NKG, JANUS Midline Fixation Screw and JANUS Penetrated Screw System
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:

<table>
<thead>
<tr>
<th>Sterilization Method</th>
<th>Temperature</th>
<th>Preconditioning</th>
<th>Exposure time</th>
<th>Drying time</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steam</td>
<td>270°F (132°C)</td>
<td>Per manufacturer’s settings</td>
<td>4 minutes</td>
<td>30 minutes</td>
</tr>
</tbody>
</table>

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

See Instructions for Use
Orthofix.com/IFU
Manufacturer

Single Use Only
Do Not Reuse
Authorized Representative

Provided Non-Sterile
Do Not Resterilize

Sterilized Using Irradiation
Lot Number

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