

## ORTHOFIX Firebird Spinal Fixation System Instructions

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**For International Use Only  
INSTRUCTIONS FOR USE**

**Important Information Please Read Prior to Use**

### **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® CDXTM Minimally Invasive**

**Spinal Fixation System JANUS®**

**Midline Fixation Screw JANUS® Fenestrated Screw**

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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 a 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:**

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, and
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 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.
4. Pregnancy.
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. (United States Use Only)
8. Patients are 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.
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, 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 causes 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.
22. The JANUS Fenestrated Screw when used with KYPHON HV-R Fenestrated Screw Cement may include adverse events of hemorrhage, hematoma, occlusion, seroma, edema, hypertension, embolism, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, damage to blood vessels, or other types of cardiovascular system compromise.
23. 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 cement in the spine including myocardial infarction, cardiac arrest, cerebrovascular accident, pulmonary embolism, and cardiac embolism. Although the majority of these adverse events present early with the postoperative period, there have been some reports of diagnoses beyond a year or more after the procedure
24. The JANUS Fenestrated Screw, when used with KYPHON HV-R Fenestrated Screw Cement, may include other reported adverse events for acrylic bone cement intended for use in the spine including leakage of the bone cement beyond the site of its intended application with an introduction into the vascular system resulting

in, but not limited to, embolism of the lung and/or heart or other clinical sequelae.

**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 that 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. The 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 the 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 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 indications, contraindications, warnings, precautions and cement preparation instruction.
27. The JANUS Fenestrated Screw when used with KYPHON HV-R Fenestrated Screw Cement may 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 bone cement is utilized, and also with the volume of bone cement used.
28. The JANUS Fenestrated Screw when used with KYPHON HV-R Fenestrated Screw Cement, monitors 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 cement. Hypotensive reactions have occurred between 10 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 perioperative 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 bicortical. It is important not to breach the pedicle wall or anterior cortex of the vertebral body to avoid cement extrusion into the retroperitoneal 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 resterilize. 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 44-9010, 44-9011, 44-9012, 44-9013, 44-9020, 44-9030, 44-9040, 44-9050, and 61-9060:**

All instruments and implants 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 reintroduction into a sterile surgical field. Cleaning can include 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.

**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.

**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.

1. Remove excess body fluids and tissue from instruments with a disposable, non-shedding wipe. Place instruments in a basin of purified water or in a tray covered with damp towels. Do not allow saline, blood, body fluids, tissue, bone fragments or other organic debris to dry on instruments prior to cleaning.
2. For optimal results, instruments should be cleaned within 30 minutes of use or after removal from the solution to minimize the potential for drying prior to cleaning.
3. Used instruments must be transported to the central supply in closed or covered containers to prevent unnecessary contamination risk.

**Note:** Soaking in proteolytic enzymatic detergents or other pre-cleaning solutions facilitates cleaning, especially in instruments with complex features and hard-to-reach areas (e.g. cannulated and tubular designs, etc.). These enzymatic detergents as well as enzymatic foam sprays break down protein matter and prevent blood and protein-based materials from drying on instruments. Manufacturers' instructions for the preparation and use of these solutions should be explicitly followed.

**Preparation for Cleaning:**

1. All instruments with moving parts (e.g., knobs, triggers, hinges) should be placed in the open position to allow access of the cleaning fluid to areas that are difficult to clean.
2. Soak the instruments for a minimum of 10 minutes in purified 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 instruments prior to manual or automated cleaning. Use a soft plastic bristle brush or a pipe cleaner to remove soil from any inner lumens.

You can also use a syringe (if appropriate) for hard-to-reach areas.

4. Enzymatic detergent should be used for manual and automated cleaning. All enzymatic detergents should be prepared at the use dilution and temperature recommended by the manufacturer. Softened tap water may be used to prepare the enzymatic detergents. The use of recommended temperatures is important for the optimal performance of the enzymatic detergent.

#### **Manual Cleaning:**

1. Completely submerge instruments in an enzymatic detergent and allow to soak for 20 minutes. Use a soft-bristled, nylon 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-bristled brush (i.e. 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 the device in the cleaning solution and sonicate for 10 minutes.
4. Rinse the instrument in purified water for at least 3 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 the 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.

#### **Automated Cleaning:**

1. Completely submerge the instruments in an enzymatic detergent and allow to soak and sonicate for 10 minutes each. Use a soft nylon-bristled 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-bristled brush (i.e. pipe cleaner). The use of a syringe or water jet will improve the flushing of difficult-to-reach areas and closely mated surfaces.
2. Remove instruments from the cleaning solution and rinse in purified water for a minimum of 1 minute. Thoroughly and aggressively flush lumens, blind holes, and other difficult-to-reach areas.
3. Place instruments in a suitable washer/disinfector basket and process through a standard instrument washer/disinfector cleaning cycle.
4. Orient instruments into the automated washer's carriers as recommended by the washer manufacturer.
5. The following minimum parameters are essential for thorough cleaning.
  - a. 2-minute prewash with cold tap water
  - b. 1-minute prewash with hot tap water
  - c. 2 minutes detergent wash with hot tap water (64-66°C/146-150°F)
  - d. 1-minute hot tap water rinse
  - e. 2-minute thermal rinse with purified water (80-93°C/176-200°F)
  - f. 1 minute purified water rinse (64-66°C/146-150°F)
  - g. 7 to 30-minute hot air dry (116°C/240°F)
6. Inspect the instruments for visible soil.

7. 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.

**Instrument End of Life Determination:**

Do not reuse Single Use instruments. Visually inspect the reusable instruments to determine if the instrument has reached the end of life. Orthofix reusable instruments have reached the End of Life when:

1. Instruments show signs of damage such as binding, bending, breakage, overt signs of wear, and/or any other conditions which may impact the devices safe and effective use.
2. Instruments intended for cutting the bone and/or tissue (e.g. tap, rasp, curette, rongeur) when any of the cutting surfaces show signs of wear such as nicks, abrasions, or otherwise dulled cutting surfaces.
3. Instruments that interface with other devices (e.g. implants, instruments, handles) – when the mating feature binds, fail to attach or fails to hold the device securely. The instrument function should be verified prior to each use.
4. Do not use instruments that reached the End of Life. Discard End of Life instruments per your hospital procedure or return to Orthofix for disposal.

**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.

**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:

Method: Steam Cycle: Gravity Temperature: 270°F (132°C) Exposure time: 15 minutes Drying time: 30 minutes Double wrapped	Method: Steam Cycle: Privacy Temperature: 270°F (132°C) Preconditioning: Per manufacturer's settings Exposure time: 4 minutes Drying time: 30 minutes Double wrapped
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**Firebird NXG, JANUS Midline Fixation Screw, and JANUS Fenestrated 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:

Sterilization Method:..... Steam  
Cycle: .....Privacy  
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 limit 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](mailto: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 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.

All third-party trademarks used herein are the trademarks of their respective owners. KYPHON® HV-R is a registered trademark of Medtronic, Inc. Orthofix is not associated with or sponsored by Medtronic, Inc.

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

**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

Single-Use Only Do Not Reuse

Catalog Number

Provided Non-Sterile

Sterilized Using Irradiation

Use By Date

Manufacturer

Authorized Representative

Do Not Resterilize

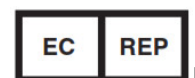
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Lot Number



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## Documents / Resources

