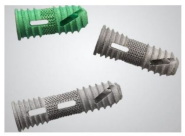

ORTHOFIX AW-18-9901 Firebird SI Fusion System Instruction Manual

Contents

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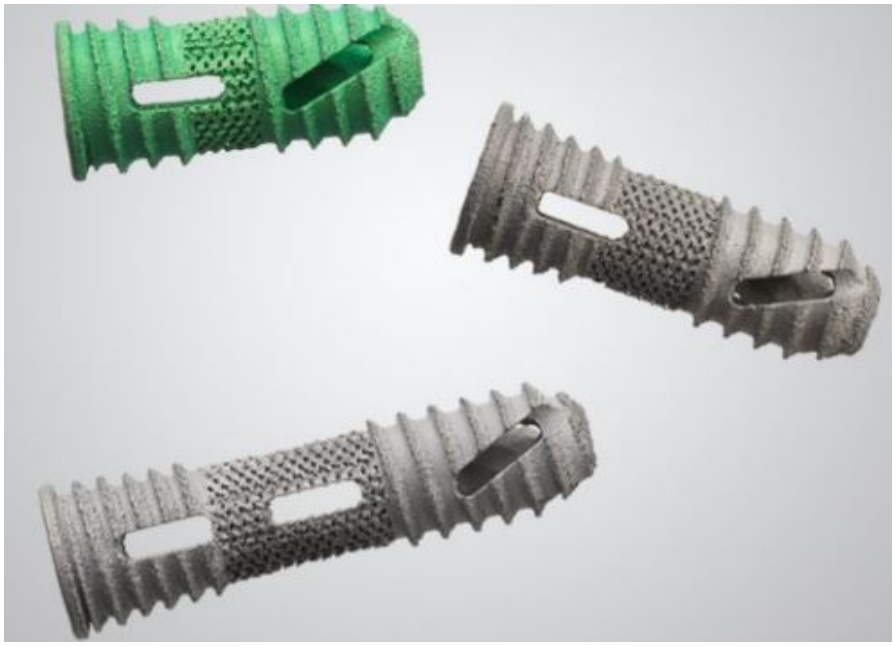


Description

The FIREBIRD SI Fusion System is a temporary, multiple component system consisting of nonsterile instruments as well as sterile, cannulated screws of various lengths and diameters with multiple fenestrations on their shafts. The FIREBIRD SI Screws are constructed from medicalgrade titanium alloy (Ti-6Al-4V ELI). The 11mm and 12mm FIREBIRD SI Screws are 3D printed with a mid-shaft porous region. The porous titanium region has open macroscopic 3D pores with a microscopically roughened surface. The FIREBIRD SI Screw allows for packing of autograft and allograft materials. FIREBIRD SI Fusion System consists of cannulated, fenestrated 9mm, 11mm, and 12mm diameter implants in lengths ranging from 25mm to 70mm. The 9mm diameter implant maintains a single pitch thread along the entire shaft of the implant. The 11mm diameter implant features a tapered proximal end and dual-pitch threads. The 12mm diameter implant maintains a single pitch thread form on the proximal and distal ends. The Steinmann Pins, Drills, and Packing Tubes are single-use devices and should be discarded after use

Indications for Use

The FIREBIRD SI Fusion System is intended for fixation of sacroiliac joint disruptions and intended for sacroiliac joint fusion for conditions including;

1. Sacroiliac joint disruptions
2. Degenerative sacroiliitis
3. To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion
4. Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint

Contraindications:

The FIREBIRD SI Fusion System is contraindicated for use in patients with:

1. Open wounds, infection, presence of tumor, pregnancy, osteoporosis, certain metabolic disorders affecting osteogenesis, certain inflammatory/neuromuscular conditions, and certain neuromuscular deficits which would place an unusually heavy load on the device during the healing period.

2. The implant is made from Ti-6Al-4V ELI (medical-grade titanium alloy). The fixation implant is contraindicated in any individual with a known or suspected allergy, sensitivity or intolerance to metal.

Potential Adverse Events

Potential adverse events include, but are not limited to:

1. Allergic reaction or metal sensitivity to foreign body.
2. Cardiovascular system compromise.
3. Death.
4. Decrease in bone density due to stress shielding.
5. Device bending, disassembly, fracture, loosening, migration and/or retropulsion, or subsid-ence.
6. Dural tears, neural structure injury.
7. Implant migration with or without bone fracture.
8. Fracture of pelvis or sacrum.
9. Gastrointestinal complications (i.e., ileus or bowel perforation).
10. Hemorrhage.
11. Incisional complications (i.e., dehiscence, hematoma).
12. Infection (Incisional or implant site).
13. Loss of spinal mobility or function.
14. Malfunction of fixation device and/or instruments.
15. Malposition of the fixation device.
16. Neurological injury/deficit which may range from paresthesias to muscle paralysis, loss of rectal or bladder sphincter control, radiculopathies.
17. Organ, connective tissue or nerve damage.
18. Pain, discomfort or abnormal sensation due to device presence.
19. Persistent low back pain.
20. Reproductive system compromise.
21. Screw back-out or breakage possibly leading to local pain, perforation or irritation of adjacent structures.
22. Sepsis.
23. Urological compromise (i.e., infection/retention).
24. Vascular injury.
25. Failure to osseointegrate.

Warnings and Precautions

1. The devices should only be used by healthcare professionals who have been trained in the use of this device. Information on laboratory and clinical training, as well as additional brochures with a detailed description of proper surgical technique, may be obtained from Orthofix. See the FIREBIRD SI Fusion System Surgical Manual for instructions on the implant procedure.
2. Infection may occur immediately following implant fixation, fusion, or a long time afterwards due to transient bacteremia such as caused by dental treatment(s), endoscopic examination or any other minor surgical procedure. To avoid infection at the implant fixa-tion, or fusion site, it may be advisable to use antibiotic prophylaxis before and/or after such procedures.

3. Women of childbearing potential should be cautioned that vaginal delivery of a fetus may not be advisable following SI joint fixation and/or fusion. If pregnancy occurs, the woman should review delivery options with her obstetrician.
4. If the screw has been in place for a sufficient amount of time for bone to have grown in to the screw, removal may not be feasible.
5. Do not reuse implants; discard used, damaged, or otherwise suspect implants.
6. Single use only. Reuse of devices labeled as single-use (implants, drills, tacks, trial rods, etc.) could result in injury or reoperation due to breakage or infection.
7. 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.
8. 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 in-tended use, indications for use or for use that in contraindicated. Failure to use the system as indicated could detrimentally affect the performance of its components.

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 ex-tends approximately 8-mm from this device when imaged with a gradient echo pulse sequence and a 3-Tesla MR system.

Cleaning

FIREBIRD SI Fusion System 11mm and 12mm diameter implants are provided STERILE. Please discard all opened and unused implants.
FIREBIRD SI Fusion System 9mm diameter implants are provided either in sterile packaging or as non-sterile. Only the non-sterile implants require sterilization prior to use. Do not re-sterilize sterile packaged implants. 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.
Instruments are provided clean but not sterile. 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 the 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 tow-els. 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 solution to minimize the potential for drying prior to cleaning.
3. Used instruments must be transported to the central supply in closed or covered contain-ers to prevent unnecessary contamination risk.

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 which are difficult to clean.
2. Soak 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 instru-ments 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 use a syringe (if appropriate) for hard to reach areas.
4. Orient instruments in the automated washer's carriers as recommended by the washer manufacturer.

Instructions for Disassembly

1. **2 Pin Parallel Guide Plate (18-3012):**
   There are three parts to the 2 Pin Parallel Guide Plate Assembly: 1. 2 Pin Parallel Guide Plate (18-3012), 2. Large Radiolucent Tube (18-3014) or Large Radiolucent Tube, Short (18-3020), and 3. Small Radiolucent Tube (18-3013) and Small Radiolucent Tube, Short (18-3019). The 2 Pin Parallel Guide Plate requires disassembly prior to cleaning using the following steps:
   - a. Remove the Large Radiolucent Tube from the 2 Pin Parallel Guide Plate. Do not discard.
   - b. Remove the Small Radiolucent Tube from the 2 Pin Parallel Guide Plate. Do not discard.
2. **3 Pin Parallel Guide Plate (18-3016):**
   There are four parts to the 3 Pin Parallel Guide Plate Assembly: 1. 3 Pin Parallel Guide Plate (18-3016), 2. Large Radiolucent Tube (18-3014) or Large Radiolucent Tube, Short (18-3020), and 3. Two Small Radiolucent Tubes (18-3013) or two Small Radiolucent Tubes, Short (18-3019). The 3 Pin Parallel Guide Plate requires disassembly prior to cleaning using the following steps:
   - a. Remove the Large Radiolucent Tube from the 3 Pin Parallel Guide Plate. Do not discard.
   - b. Remove the two Small Radiolucent Tubes from the 3 Pin Parallel Guide Plate. Do not discard.
3. **Drill (18-3100, 18-3101, 18-3102) and Adjustable Collar (18-3011):**
   There are two parts: 1. Drill (single use only) and 2. Adjustable Collar (18-3011). The Drill and Adjustable Collar require disassembly prior to cleaning using the following steps:
   - a. Disengage the Adjustable Collar from the Drill shank.
   - b. Slide the Adjustable Collar over the Drill shank to remove.
   - c. Discard the Drill, which is single use only. Do not discard the Adjustable Collar.
4. **Packing Plunger (18-3010) and Packing Tube (18-3009):**

There are two parts: 1. Packing Plunger and 2. Packing Tube (single use only). The Packing Plunger and Packing Tube require disassembly prior to cleaning using the following steps:

- a. Remove the Packing Plunger from the Packing Tube.
- b. Discard the Packing Tube, which is single use only. Do not discard the Packing Plunger.

5. **Adjustment Driver (18-3017) and Adjustment Driver Insert (18-3018):**
   There are two parts: 1. Adjustment Driver and 2. Adjustment Driver Insert. The Adjustment Driver and Adjustment Driver Insert require disassembly prior to cleaning using the follow-ing steps:
   - a. Unthread the Adjustment Driver Insert from the Adjustment Driver.
   - b. Remove the Adjustment Driver Insert from the Adjustment Driver.

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 mini-mum 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 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 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 un-til 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). Use of a syringe or water jet will improve 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 in 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 instrument has reached end of life. Orthofix reusable instruments have reached 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 bone and/or tissue (i.e. 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. implant, instruments, handle) – when the mating feature binds, fails to attach or fails to hold the device securely. The instrument function should be verified prior to each use.
4. Do not use instruments which reached End of Life. Discard End of Life instruments per your hospital procedure or return to Orthofix for disposal.

Sterilization

FIREBIRD SI Fusion System 11mm and 12mm diameter implants are provided STERILE. FIREBIRD SI Fusion System 9mm diameter implants are provided either in sterile packaging or as non-sterile, which requires sterilization prior to use. Please discard all opened and unused implants. The STERILE FIREBIRD SI implants are sterilized using gamma irradiation sterilization. Do not re-sterilize these implants.

Sterilization in Orthofix Cases with Blue Wrap:
The FIREBIRD SI Fusion System non-sterile, 9mm diameter implants, 9mm Caddy (18-9092), and instruments are supplied NON-STERILE. Place all non-sterile, 9mm diameter implants in their designated location within the caddy. Place the dry instruments in the designated locations in the case (see markings on the tray surface that indicate proper storage location in the case). The FIREBIRD SI Fusion System instruments are supplied NON-STERILE. Prior to use, all instruments and 9mm Caddy should be placed in the appropriate Orthofix case (see markings on the tray surface that indicate proper storage location in the case), which will be wrapped in an FDA cleared sterilization wrap and placed in the autoclave for sterilization by the hospital using one of the following recommended cycles

- Method: Steam
- Cycle: Gravity
- Temperature: 270°F (132°C)
- Exposure time: 15 minutes
- Drying time: 30 minutes

- Double wrapped

OR

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

Sterilization in Rigid Sterilization Containers:
When using rigid sterilization containers with FIREBIRD SI Fusion System instruments, clean, inspect and prepare the rigid sterilization container according to the manufacturer’s instructions.
Select the appropriate rigid sterilization container with either a filtered or solid bottom to properly enclose the Orthofix case (recommended 23¼” long x 11¼” wide container). The following sterilization cycle has been validated:

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

Validation and routine monitoring should be performed per ANSI/AAMI ST79 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Other cycles may be used as long as they comply with the above practices and provide a sterility assurance level of 10-6.

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 care-fully checked for damage prior to use. Damaged packages or products should not be used and should be returned to Orthofix. The FIREBIRD SI Fusion System instruments and non-sterile, 9mm diameter implants are provided in a modular case specifically intended to contain and organize the system’s components. The 9mm diameter implants are organized in the caddy for easy retrieval during surgery. These cad-dies also provide protection to the 9mm diameter implants during shipping. Additionally, individ-ual 9mm diameter implants are provided in sealed poly bags with individual product labels. The system’s instruments are organized into trays within each modular case for easy retrieval during surgery. These trays also provide protection to the system components during shipping. Addition-ally, individual instruments are provided in sealed poly bags with individual product labels. FIREBIRD SI Fusion System 9mm, 11mm and 12mm diameter implants (18-09XXSP or 18-1XXXSP or 18-2XXXSP) are provided STERILE. Do not use if the package is opened or damaged, or if the expiration date has passed.

Product Complaints:

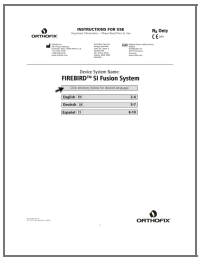
Any Healthcare Professional (e.g., customer or user of this system) who has any complaints or who has experienced any dissatisfaction with the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify Orthofix Inc., 3451 Plano Parkway, Lewisville, TX 75056, USA, by telephone at 1-214-

937-3199 or 1-888-298-5700 or by e-mail at **complaints@orthofix.com.**

Further Information:
A recommended operative technique for the use of this system is available upon request from Orthofix at the phone numbers provided above.

Latex Information:
The implants, instruments and/or packaging material for the FIREBIRD 3D SI Fusion 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 (USA) restricts these devices to sale by or on the order of a physician.

Documents / Resources

	**ORTHOFIX AW-18-9901 Firebird SI Fusion System** [pdf] Instruction Manual AW-18-9901, Firebird SI Fusion System

References

- **EU Authorized Representative Services For Medical Devices**
- **Medical Devices & Solutions - Orthofix**