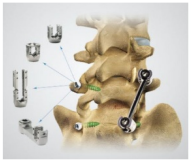

ORTHOFIX Spinal Fixation System Instructions

Contents

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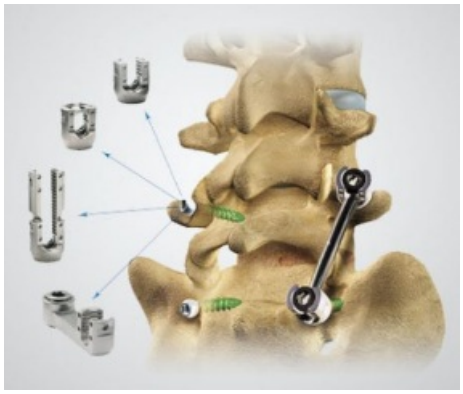


Description

The Spinal Fixation System is a temporary, titanium alloy, multiple component system comprised of a variety of non-sterile, single use components that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screws and hooks to the non-cervical spine. The Spinal Fixation System consists of an assortment of screws, hooks, rods, spacers, staples, washers, dominos, lateral offsets, and cross-connectors. The Spinal Fixation System titanium implants are not compatible with components or metal

from any other manufacturer's system.

Levels of Use:
The Spinal Fixation System is intended for non-cervical use in the spine. When used as aA non-pedicle anterolateral fixation system it may be used from levels T1 to S1. When used with pedicle screw fixation, the Spinal Fixation System will be used at L5-S1, with the device fixed or attached to the lumbar and sacral spine (levels of pedicle screw fixation are L3 and below). When used as a posterior non-pedicle fixation system it may be used from levels T1 to S1. When used as a non-pedicle anterolateral screw fixation system to the non-cervical spine, the staple and washer may be used from levels T6 to L5.

Indications for Use:

Indications:	**Applicability:**
The Spinal Fixation System is intended for non-cervical use in the spi ne. The Spinal Fixation System, when used for pedicle screw fixation, is intended only for patients: 1. Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 jo int. 2. Who are receiving fusion using autogenous bone graft only. 3. Who are having the device fixed or attached to the lumbar and sa cral spine (L3 and below). 4. Who are having the device removed after the development of a s olid fusion mass.	Pedicle Screws, Rods, Cross Connecto rs, Dominos, Lateral Offsets, and Spac ers.
The Spinal Fixation System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and s tabilization of spinal segments, as an adjunct to fusion in the treatme nt of the following acute and chronic instabilities or deformities of the t horacic, lumbar and sacral spine: 1. Degenerative spondylolistheses with objective evidence of neurol ogic impairment. 2. Fracture. 3. Dislocation. 4. Scoliosis. 5. Kyphosis. 6. Spinal tumor. 7. Failed previous fusion (pseudoarthrosis).	Pedicle Screws, Rods, Cross Connecto rs, Dominos, Lateral Offsets, and Spac ers.

The Spinal Fixation System, when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following i ndications: 1. Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radi ographic studies). 2. Spondylolisthesis. 3. Spinal stenosis. 4. Spinal deformities (i.e., scoliosis, kyphosis, and/ or lordosis). 5. Tumor. 6. Pseudoarthrosis. 7. Failed previous fusion. 8. Trauma (i.e., fracture or dislocation).	Pedicle Screws, Rods, Cross Connecto rs, Dominos, Lateral Offsets, Spacers, Staples, and Washers.

Indications:	**Applicability:**
The Spinal Fixation System, when used for posterior non- pedicle scr ew fixation system of the non-cervical spine, is intended for the follow ing indications: 1. Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radi ographic studies). 2. Spondylolistheses. 3. Spinal stenosis. 4. Spinal deformities (i.e., scoliosis, kyphosis, lordosis). 5. Tumor. 6. Pseudoarthrosis. 7. Failed previous fusion. 8. Trauma (i.e., fracture or dislocation).	Hooks, Rods, Cross Connectors, and D ominos.

Note: For all of these indications, bone graft must be used.

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 are unwilling or unable to follow post-operative care instructions.
8. 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. Device component fracture.
2. Loss of fixation.
3. Non-union.
4. Fracture of the vertebra.
5. Neurological injury.
6. Vascular or visceral injury.
7. Early or late loosening of any or all of the components.
8. Disassembly and/or bending of any or all of the components.
9. Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, straining, tumor formation, and/or auto-immune disease.
10. Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain.
11. Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
12. Infection.
13. Pain, discomfort, or abnormal sensations due to the presence of the device.
14. Hemorrhage.
15. sation of any potential growth of the operated portion of the spine.
16. Death.

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

Warnings and Precautions:
The surgeon should be aware of the following when using implants:

1. The safety and effectiveness of pedicle screw spinal 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 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.
2. When used as a pedicle screw implant system, this device system is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar – first sacral (L5-S1) vertebral joint.
3. The screws of this device system are not intended for insertion into the pedicles to facilitate spinal fusions above the L5-S1 joint.
4. Benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.

5. 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.
6. 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.
7. Non-sterile; the screws, hooks, rods, dominos, lateral offsets, spacers, staples, washers, locking nuts, cross connectors, and instruments are sold non-sterile, and therefore, must be sterilized before use.
8. To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used.
9. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
10. . Excessive torque applied to the screws may strip the threads in the bone.
11. 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.
12. 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.
13. 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 on the performance of the system.
14. 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.

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:
Instruments and 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.All instruments must be thoroughly cleaned after each use. Cleaning may be done using vali-dated hospital methods or following the validated cleaning process described below. None of the instruments in 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 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. Manufacturer's instructions for 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. Use of recommended temperatures is important for optimal performance of 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 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 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). 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 into the automated washer's carriers as recommended by the washer manufacturer.
5. The following minimum parameters are essential for thorough cleaning.
6. 2 minute prewash with cold tap water
7. 1 minute prewash with hot tap water
8. 2 minute detergent wash with hot tap water (64-66°C/146-150°F)
9. 1 minute hot tap water rinse
10. 2 minute thermal rinse with purified water (80-93°C/176-200°F)
11. 1 minute purified water rinse (64-66°C/146-150°F)
12. 7 to 30 minute hot air dry (116°C/240°F)
13. Inspect the instruments for visible soil.
14. 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.

Torque Limiting Instrument Maintenance

- If a torque-limiting handle has been dropped, impacted or used incorrectly, return to Orthofix.
- Torque-limiting handles require maintenance at minimum, every three years or per your service agreement. Please return your torque limiting handles to Orthofix for required maintenance.

Instrument End of Life Determination:
Do not reuse Single Use instruments. Visually inspect the reusable instruments to determine if the 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 (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, fails to attach or fails to hold the device securely. The instrument function should be verified prior to each use. 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:
The Spinal Fixation System instruments and implants are provided NON-STERILE. Prior to use, all instruments and implants should be placed in the appropriate Orthofix case which will be wrapped in a FDA cleared sterilization wrap and sterilized by the hospital using one of the following recommended cycles:

- Method: Steam
- Cycle: Gravity
- Temperature: 250°F (121°C)
- Exposure time: 30 minutes
- Method: Steam
- Cycle: Prevac
- Temperature: 270°F (132°C)
- Exposure time: 8 minutes

Physician Information: Preoperative:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Correct selection of the implant is extremely important.
4. Use care in handling and storage of implant components. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided. These, in turn, may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Inspection should be made to determine if components have been damaged during storage or previous procedures.
5. An adequate inventory of implant sizes should be available at the time of surgery.
6. Certain special surgical instruments are required to perform this surgery. Review of the use and handling of these instruments is very important.

Intraoperative:

1. The primary goal of this surgery is to arthrodese selected vertebrae. Adequate exposure, bony preparation and grafting is essential to achieving this result.
2. Whenever possible, use pre-cut rods of the length needed. The rods should not be repeatedly or excessively bent any more than absolutely necessary. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched in any way. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field.
3. The use of two rods and cross connecting the rods will provide a more rigid construct.
4. The placement of screws should be checked radiographically prior to assembly of the rod construct.
5. Care should be taken when positioning the implants to avoid neurological damage.
6. To facilitate proper fusion below and around the location of the instrumentation, a bone.
7. Confirm that the rods are fully seated in the bottom of the screw head. Rods that are not fully seated may

prevent the device from locking together.

8. Before closing the soft tissues, all of the set screws should be tightened firmly with a torque wrench or screwdriver according to the operative technique. Recheck the tightness of all screws and nuts to make sure that none loosened during the tightening of the other set screws. Failure to do so may cause loosening of the other components.

Postoperative:

1. Detailed instructions on the use and limitations of the implant should be given to thepatient. The patient must be made aware of the limitations of the implant. Physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation device.
2. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components.
3. Surgical implants must never be reused. Any retrieved devices should never be reused in another surgical procedure. The retrieved parts should be handled and disposed of in such a manner as to ensure that reuse is not possible.
4. To allow the maximum potential for a successful surgical result, the patient or device should not be exposed to mechanical vibration that may loosen the device construct.
5. These implants are temporary internal fixation devices. Internal fixation devices are designed to assist in the stabilization of the operative site during normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. In most cases removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, complication may occur as follows:
6. Corrosion, with localized tissue reaction or pain.
7. Migration of implant position resulting in injury.
8. Risk of injury from postoperative trauma.
9. Bending, loosening and/or breakage, which could make removal impractical or difficult.
10. Pain, discomfort or abnormal sensations due to the presence of the device.
11. Possible increased risk of infection.
12. Bone loss caused by stress shielding.

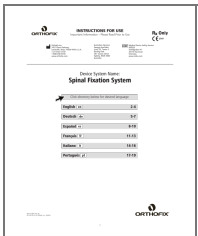
Packaging:
Packages for each of the components should be intact upon receipt. If a consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for damage prior to use. Damaged packages or products should not be used and should be returned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

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 the 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 Spinal Fixation 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 Spinal Fixation System [pdf] Instructions Spinal Fixation System

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- Medical Devices & Solutions - Orthofix