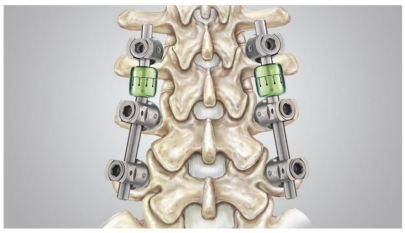
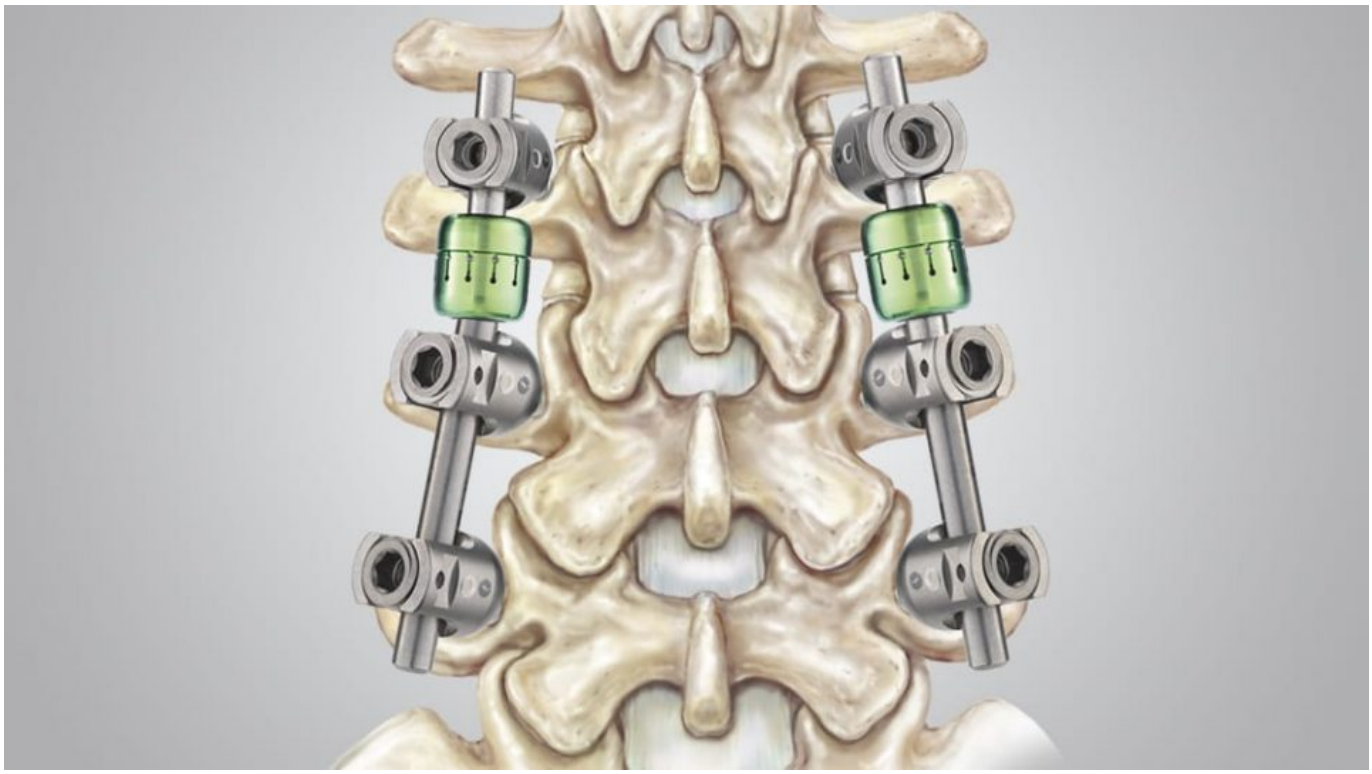


ORTHOFIX TDX Posterior Dynamic Stabilization System Instruction Manual

ORTHOFIX TDX Posterior Dynamic Stabilization System



Contents

Description:

The TDX Posterior Dynamic Stabilization System is a STERILE, single-use only motion preserving dynamic rod component used in conjunction with an Orthofix posterior pedicle screw system that allows a surgeon to build a spinal implant construct. The dynamic rod attaches to the vertebral body by means of screws and hooks to the non-cervical spine and consists of a polyurethane core secured in an implant-grade titanium housing.

Indications for Use:

When used in skeletally mature patients with the Orthofix FirebirdTM Spinal Fixation System family of posterior pedicle screw systems or the Orthofix Spinal Fixation System (SFS) posterior pedicle screw system, the TDX Posterior Dynamic Stabilization System is intended to provide immobilization and stabilization of non-cervical spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities using autogenous graft only:

1. Degenerative spondylolisthesis with objective evidence of neurologic impairment.
2. Kyphosis.
3. Failed previous fusion (pseudoarthrosis).

The TDX Posterior Dynamic Stabilization System is to be installed in pairs with the single motion segment at the same level and within a longer construct.

When used as part of a pedicle screw implant system, the TDX Posterior Dynamic Stabilization System is intended only for grade 3 or 4 spondylolisthesis at the fifth lumbar first sacral (L5-S1) vertebral joint.

Please refer to the Firebird Spinal Fixation System or Spinal Fixation System (SFS) Instructions for Use (IFU) for a complete list of Indications for Use.
Note: For all indications, autogenous 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 unwilling or unable to follow post-operative care instructions.
8. If implanting the TDX Posterior Dynamic Stabilization System, any known allergy to titanium, polyurethane, or ethylene oxide residuals.
9. Any circumstances not listed under the heading indications.

Potential Adverse Events:

All of the possible adverse events associated with spinal fusion surgery without instrumentation are possible. With instrumentation, a listing of possible adverse events includes, but is not limited to:

1. 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 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. Cessation of any potential growth of the operated portion of the spine. Death.

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

Warnings and Precautions:

1. 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

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.

2. The benefit of spinal fusions utilizing any pedicle screw fixation system has not been adequately established in patients with stable spines.
3. Potential risks identified with the use of this device system, which may require additional surgery, include: device component fracture, loss of fixation, nonunion, fracture of the vertebra, neurological injury, and vascular or visceral injury.
4. 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.
5. The system instruments are sold non-sterile, and therefore must be sterilized before use.
6. The TDX dynamic rod is sold STERILE, and therefore should not be re-sterilized.
7. The system requires the use of autogenous bone graft. 8. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
8. 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.
9. The implantation of the system should be performed only by experienced spinal surgeons with specific training in the use of the dynamic rod as part of a pedicle screw spinal system.
10. Physicians/Surgeons should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system.
11. The safety and effectiveness of this device for the indication of spinal stabilization without fusion have not been established.
12. 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:

The TDX Posterior Dynamic Stabilization System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of TDX Posterior Dynamic Stabilization System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Cleaning:

TDX Posterior Dynamic Stabilization System implants are provided STERILE. Do not use the implant if the package is opened or damaged or if the expiration date has passed. Please discard all open and unused implants. Do not re-sterilize an opened and unused implant.

All instruments must be thoroughly cleaned and sterilized after each use. Cleaning may be done using validated hospital methods or following the validated cleaning processes described below.

None of the instruments 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.
   a. 2 minute prewash with cold tap water
   b. 1 minute prewash with hot tap water
   c. 2 minute 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.

Torque Limiting Instrument Use:

- Never use torque limiting drivers in the counter-clockwise (CCW) direction to loosen a fastener
- Only use torque limiting handle as intended per the operative technique
- Never impact on torque limiting handles or use as an impacting device on other devices
- Never use a torque limiting handle as a prying tool

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.
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:

The TDX Posterior Dynamic Stabilization System Instruments should be sterilized by the hospital using one of the following recommended cycles:

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

The TDX Posterior Dynamic Stabilization System implants are provided STERILE. They are sterilized using Ethylene Oxide sterilization. Do not re-sterilize.

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 TDX Posterior Dynamic Stabilization System instruments are provided in a modular case specifically intended to contain and organize the system's components. 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. Additionally, individual instruments are provided in sealed poly bags with individual product labels.

TDX Posterior Dynamic Stabilization System implants 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, 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 TDX Posterior Dynamic Stabilization 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: The TDX Posterior Dynamic Stabilization System has not been cleared by the US Food and Drug Administration and is not available in the United States.

	See Instructions for Use
	Orthofix.com/IFU
	Single Use Only Do Not Reuse
	Catalogue Numbe
	Sterilized Using Ethylene Oxide
	Lot Number
	Use By Date
	Manufacturer
	Authorized Representative
	Do Not Resterilize
	Serial Number

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ORTHOFIX®

Documents / Resources

	ORTHOFIX TDX Posterior Dynamic Stabilization System [pdf] Instruction Manual TDX Posterior Dynamic Stabilization System, TDX, Posterior Dynamic Stabilization System, Stabilization System, Dynamic Stabilization System, Posterior System

References

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