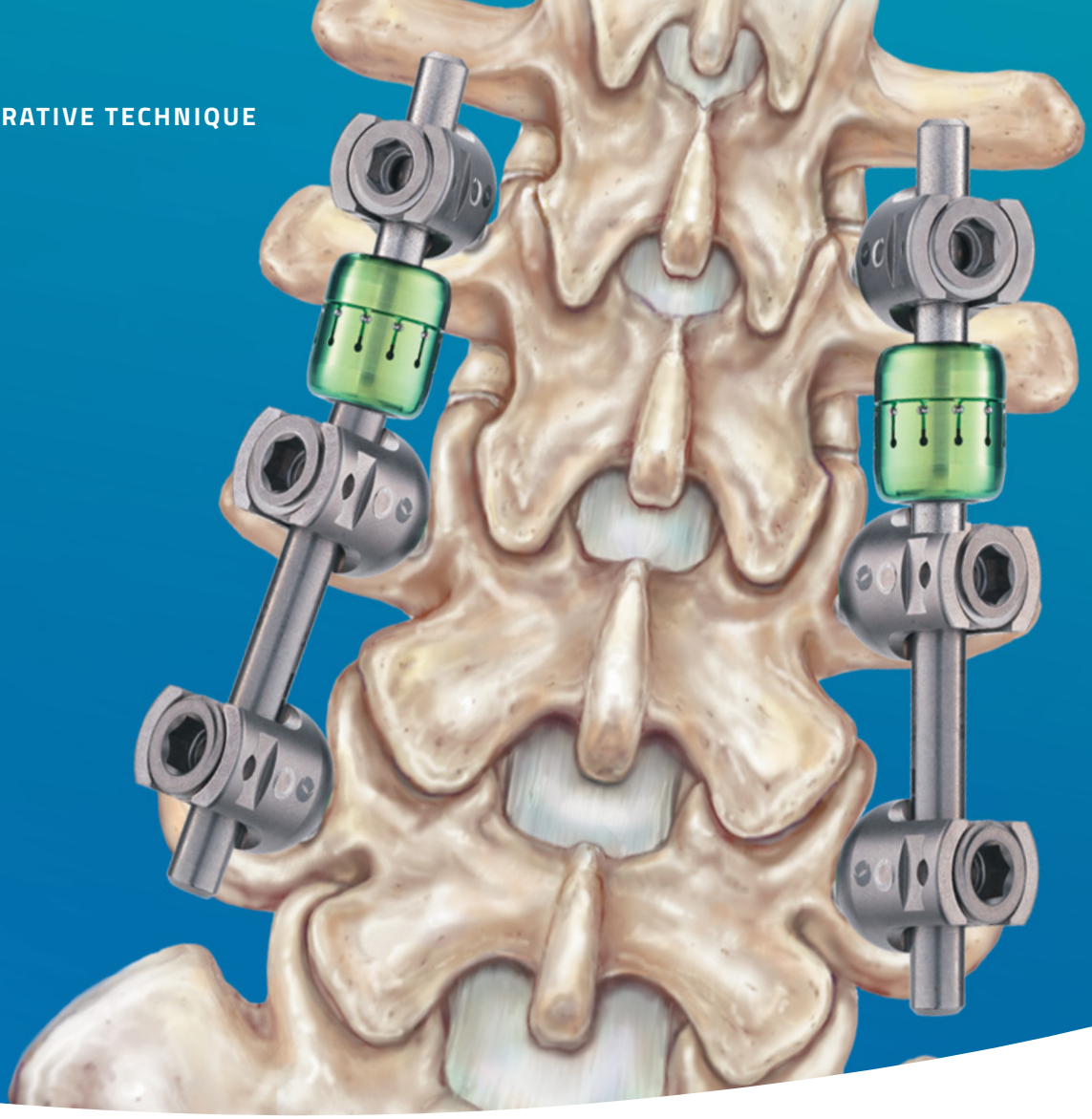
OPERATIVE TECHNIQUE



MICHELSON TECHNOLOGY AT WORK

TDX™

Posterior Dynamic Stabilization System

This device is not cleared by the FDA
for distribution in the United States.

ORTHOFIX®

TABLE OF CONTENTS

Orthofix wishes to thank the following surgeons for his contribution to the development of the technique:

Dr. Paul M. Keller
Atlantic Orthopedic Group
Melbourne, FL

Dr. John P. Masciale
Corpus Christi, TX

Dr. Faheem Sandhu
Washington, DC

The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see Instructions for Use for the complete list of indications, warnings, precautions, and other important medical information.

INTRODUCTION

The Orthofix TDX Posterior Dynamic Stabilization System is a new posterior dynamic rod allowing natural movements in the treated segments of the lumbar spine. Together with the company's Firebird® pedicle screws, also available with a hydroxyapatite (HA) coating designed to optimize bone fixation, the rods can be used for single level motion preservation treatment, or as an adjunct to fusion.

The TDX Posterior Dynamic Stabilization System is intended to provide posterior stabilization while allowing small degrees of natural movement of the lumbar spine. As a single level treatment, the TDX rods enable movements in flexion, extension, lateral bending and rotation. Used as an adjunct to fusion, the TDX rods render dynamic stabilization while providing traditional rigid fixation in adjacent levels.

TDX™
Posterior Dynamic Stabilization

FEATURES AND BENEFITS

- Implantation through known Firebird® Spinal Fixation System surgical technique.
- Can be used in conjunction with rigid fixation.
- Pre-assembled for reduced insertion time.
- As a single level treatment allows for natural movement of the lumbar spine.

HA COATED SCREWS

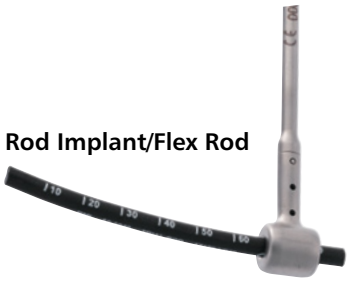
- Hydroxyapatite (HA) coated screws that are designed to facilitate osseointegration and improve stability of the construct.

INSTRUMENTS

- Precision instruments with ergonomic handles improve tactile feel.

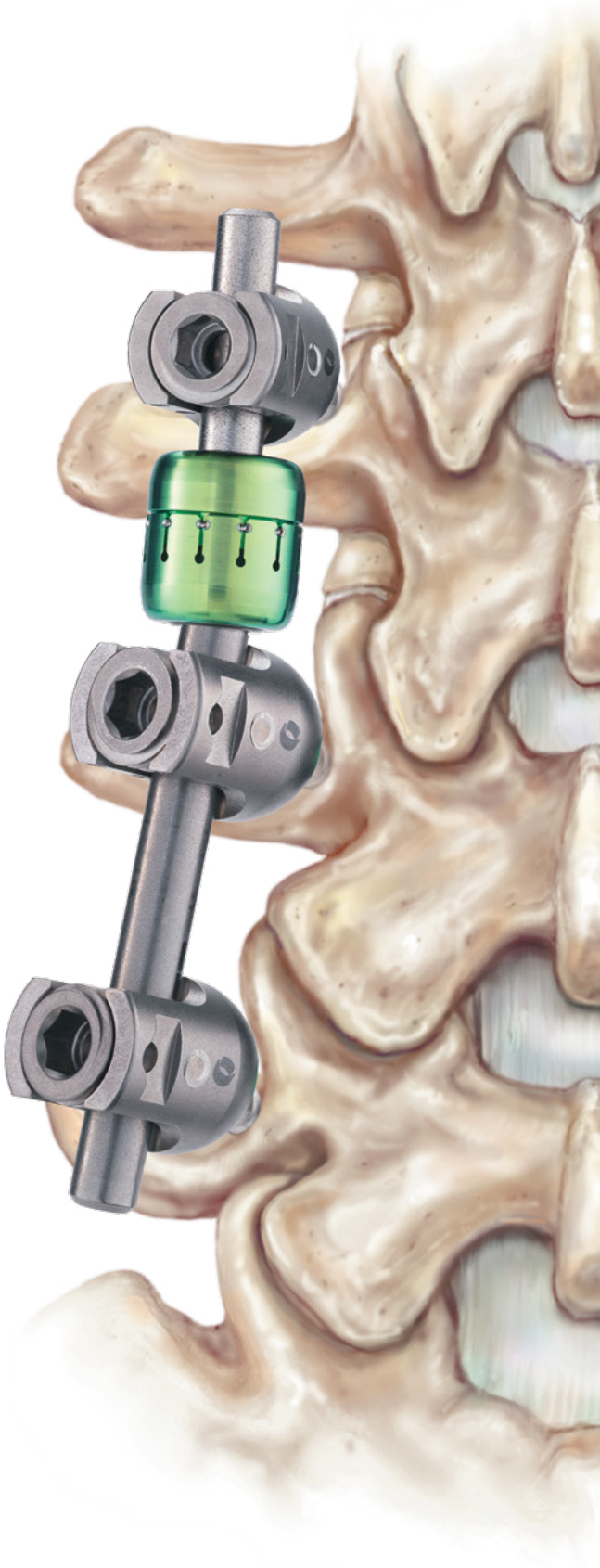
Counter Torque Wrench

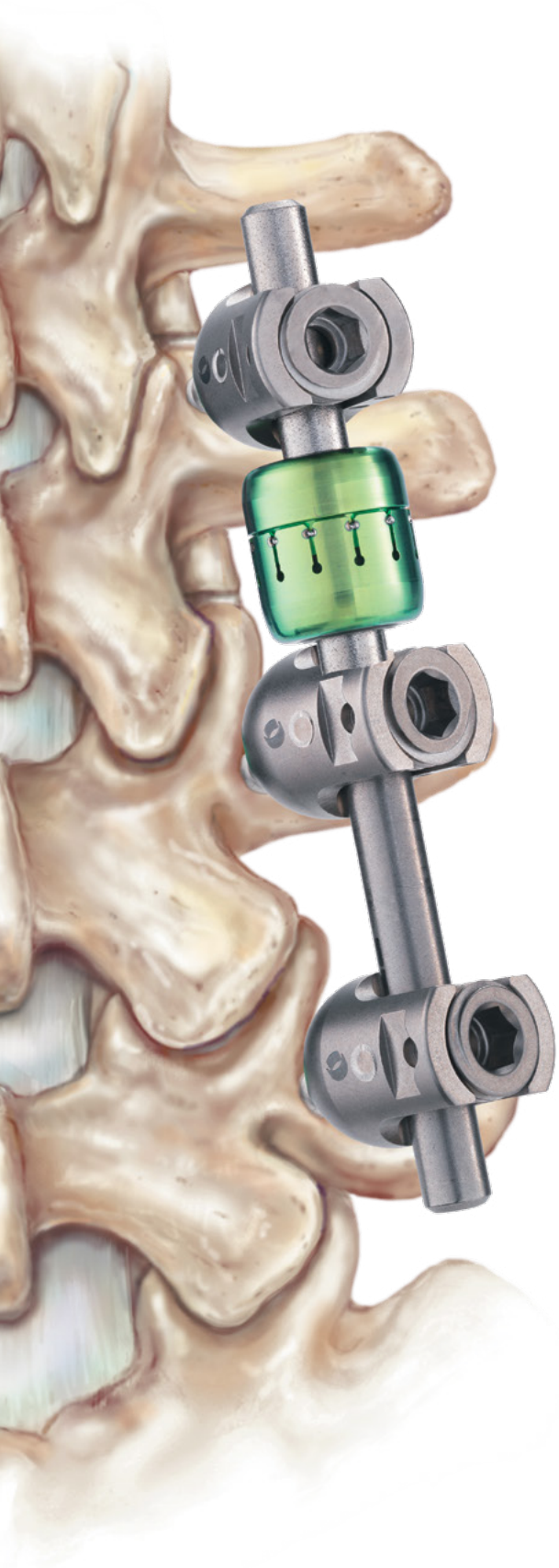
Flex Rod Implant/Flex Rod



Implant Trial

Inserter/Holder



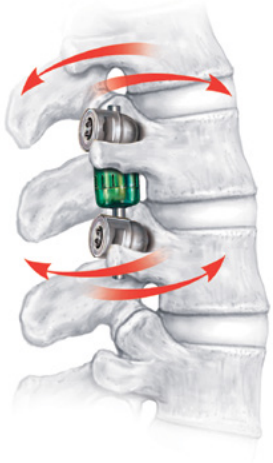


NATURAL MOVEMENT OF THE LUMBAR SPINE

The Orthofix TDX Posterior Dynamic Stabilization System is a posterior dynamic rod allowing natural movements in the treated segments of the lumbar spine. Together with the company's Firebird pedicle screws, also available with a hydroxyapatite (HA) coating designed to optimize bone fixation, the rods can be used for single level motion preservation treatment, or as adjunct to fusion.

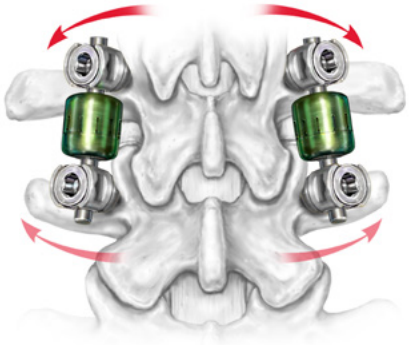
The TDX Posterior Dynamic Stabilization System is intended to provide posterior stabilization while allowing small degrees of natural movement of the lumbar spine. As a single level treatment, the TDX rods enable movements in flexion, extension, lateral bending and rotation. Used as an adjunct to fusion, the TDX rods render dynamic stabilization while providing traditional rigid fixation in adjacent levels.

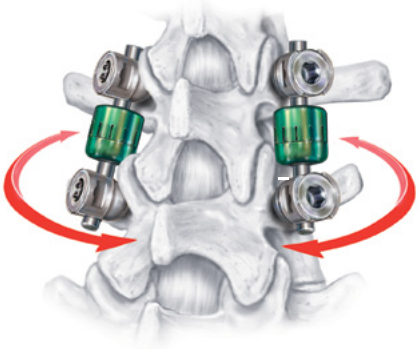
BIOMECHANICAL PERFORMANCE



Flexion-Extension

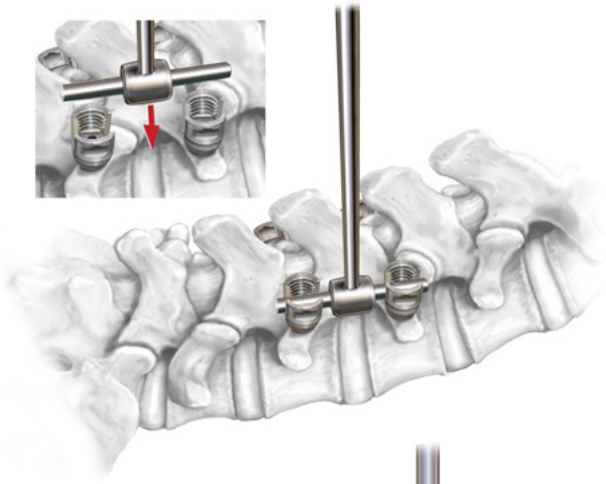
Lateral Bending





Axial Rotation

Fig. 1a



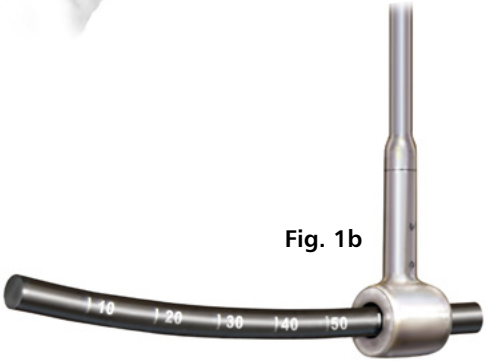


Fig. 1b

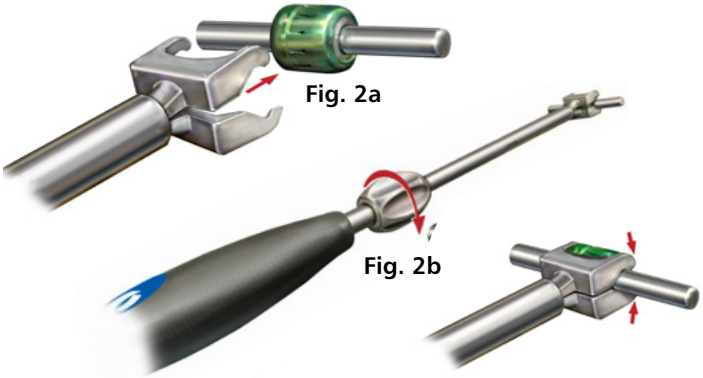


Fig. 2a

Fig. 2b

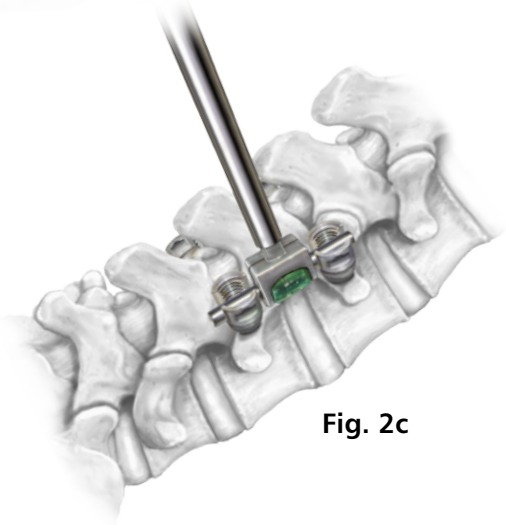


Fig. 2c

1. IMPLANT TRIALING

Note: Please refer to the Firebird Spinal Fixation Operative Technique regarding steps for pedicle preparation prior to screw insertion, loading bone screws onto the respective drivers and screw insertion and adjustment.

To help determine the proper TDX implant size, choose one of the available implant trials (16-1045, 16-1050 and 16-1055) and insert between the two pedicle screw heads **(Fig. 1a)** Trials are available in 45, 50 and 55mm. The Trials end geometry closely matches the implant geometry for optimal size evaluation.

When a longer implant is required and needs contouring, the Flex-Rod implant Trial (16-1040) **(Fig. 1b)** can be utilized. Insert a Flex-Rod into the barreled end of the device and place between the pedicle screws. Bend the flexible rod manually until the proper contouring has been achieved. The flexible rod may now be used as a template for contouring the TDX Implant using a Rod Bender.

2. INSTALL IMPLANT

Remove implant from sterile package and install onto Implant Holder/Inserter (16-1000). Turn knob clockwise to clamp down firmly onto TDX implant **(Fig. 2a and Fig. 2b)**. Place implant between pedicle screws with rod segments of implant sitting inside the pedicle screw slots **(Fig. 2c)**. Do not remove Implant Holder/Inserter as it helps to maintain linear alignment and rotational orientation of the rod.

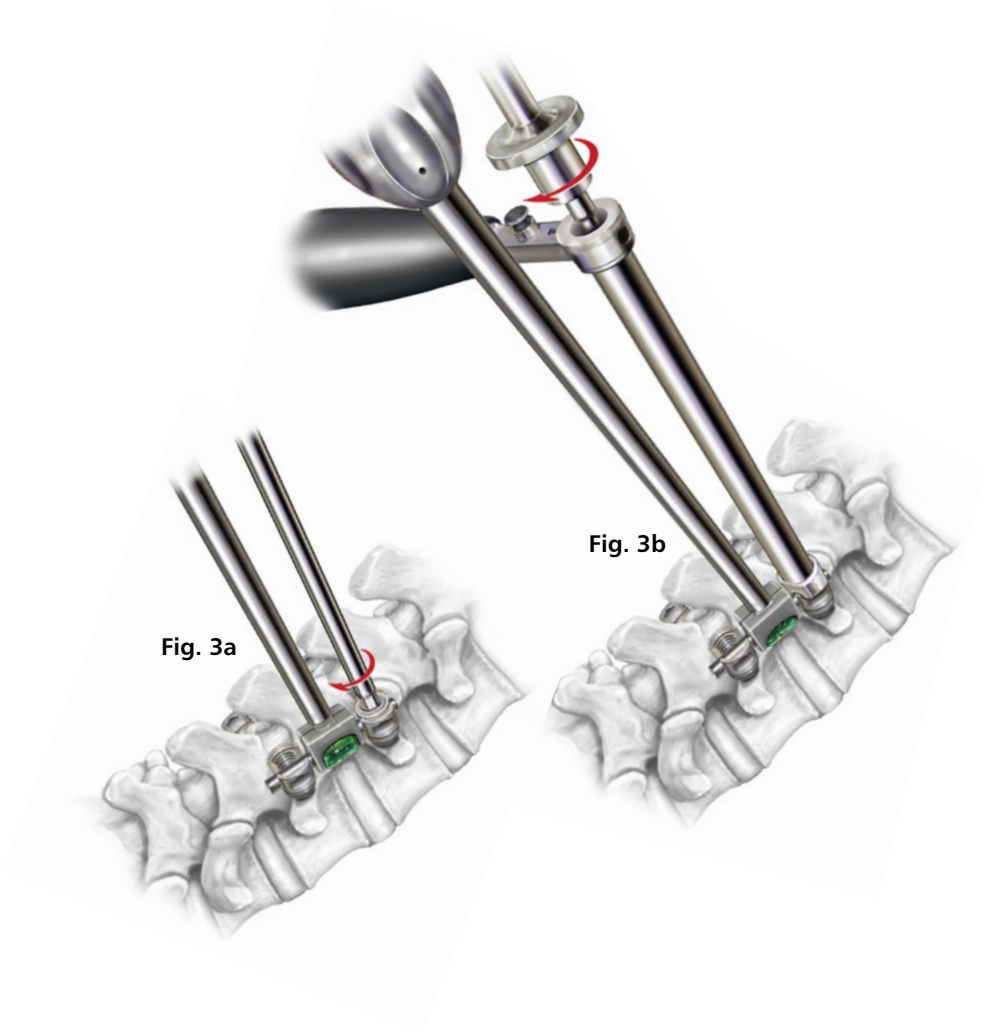


Fig. 3a

Fig. 3b

3. SECURE TDX IMPLANT

Use the set screw driver/holder (54-1060) to insert the set screw.

Cross-threading of the set screw and the head can be avoided by first rotating the set screw counter clockwise. Once aligned, advance the set screw into the head. **(Fig. 3a)**

Slide the canulated set screw counter torque wrench over the multi-axial head and onto the rod, slide the set screw driver (55-1060) through the counter torque wrench and engage the set screw. **(Fig. 3b)**

To finalize construct tightening, apply 100 in-lbs of torque to each set screw with the deflection beam torque wrench (55-1065). The torque limiting (snap style) T-handle torque wrench 100 in-lb (55-1068) may be used to secure the construct.

After tightening, remove the TDX Implant Holder/Inserter.

REMOVAL PROCEDURE

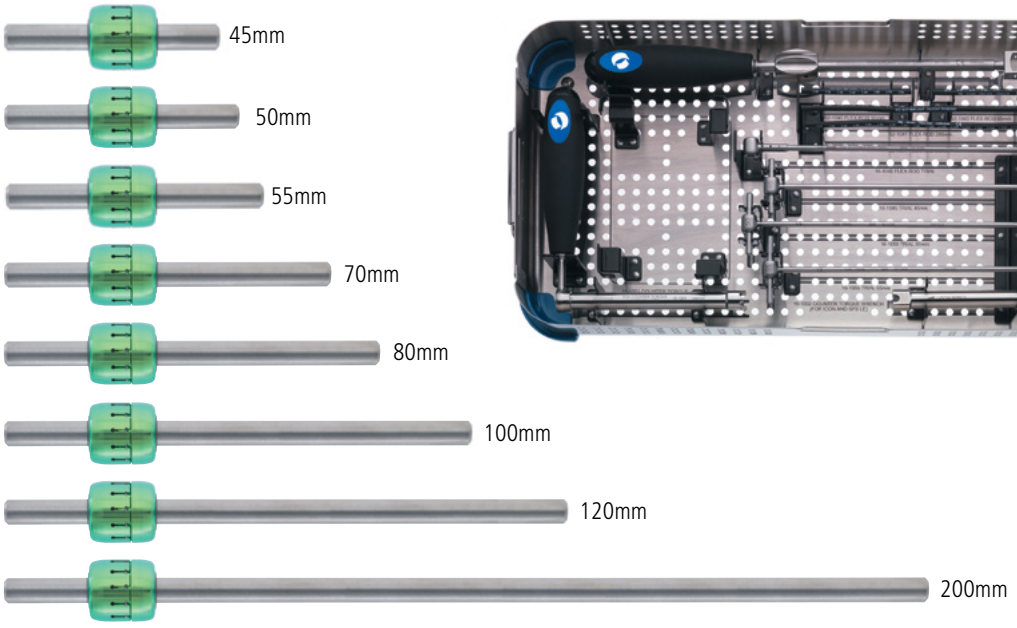
Removal of implants should be performed as outlined in the Firebird Spinal Fixation Operative Technique.

TDX RODS

16-2045 TDX Rod, 45mm
16-2050 TDX Rod, 50mm
16-2055 TDX Rod, 55mm
16-2070 TDX Rod, 70mm
16-2080 TDX Rod, 80mm
16-2100 TDX Rod, 100mm
16-2120 TDX Rod, 120 mm
16-2200 TDX Rod, 200mm

TDX INSTRUMENTS

16-0001 Instrument Case
16-1000 Inserter/Holder
16-1001 Counter Torque Wrench-Firebird
16-1002 Adjustable Counter Torque Wrench
16-1040 Flex Rod Implant Trial
16-1045 45mm Implant Trial
16-1050 50mm Implant Trial
16-1055 55mm Implant Trial
52-1040 90mm Flexible Trial Rod
52-1041 200mm Flexible Trial Rod



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

Indications for Use: When used with posterior pedicle screws fixation systems in skeletally mature patients, i.e., Orthofix Firebird Spinal Fixation System or Spinal Fixation System (SFS), 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, and
3. Failed previous fusion (pseudoarthrosis)

When used as 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 Orthofix 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 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, staining, 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
16. 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. 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, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.
4. Single use only
5. The TDX Posterior Dynamic Stabilization instruments are sold non-sterile, and therefore must be sterilized before use.
6. The TDX Stabilization System is sold STERILE, and therefore should not be re-sterilized.
7. The TDX Posterior Dynamic Stabilization System requires the use of autogenous bone graft.
8. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.
9. DO NOT REUSE IMPLANTS. Discard used, damaged, or otherwise suspect implants.
10. The implantation of the TDX Posterior Dynamic Stabilization System should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system.
11. Physicians / Surgeons should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact on the performance of the system.
12. The safety and effectiveness of this device for the indication of spinal stabilization without fusion have not been established.
13. Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not re-sterilize single-use implants that come in contact with body fluids.
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.

Notes

Distributed by:

Manufactured by:
Orthofix
3451 Plano Parkway
Lewisville, Texas 75056-9453 USA
214-937-2000

CE 0086

Caution: This device is not cleared by the FDA for distribution in the United States. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience. Please refer to the "Instructions for Use" supplied with the product for full information on indications for use, contraindications, warnings, precautions, adverse reactions information and sterilization.

214.937.2000
www.orthofix.com

ORTHOFIX®