

For International Use Only

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

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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 the 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, 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.

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.

INSTRUMENTS

- Precision instruments with ergonomic handles improve tactile feel.

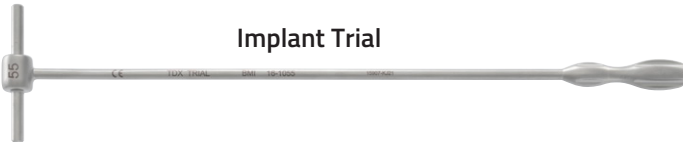
Counter Torque Wrench



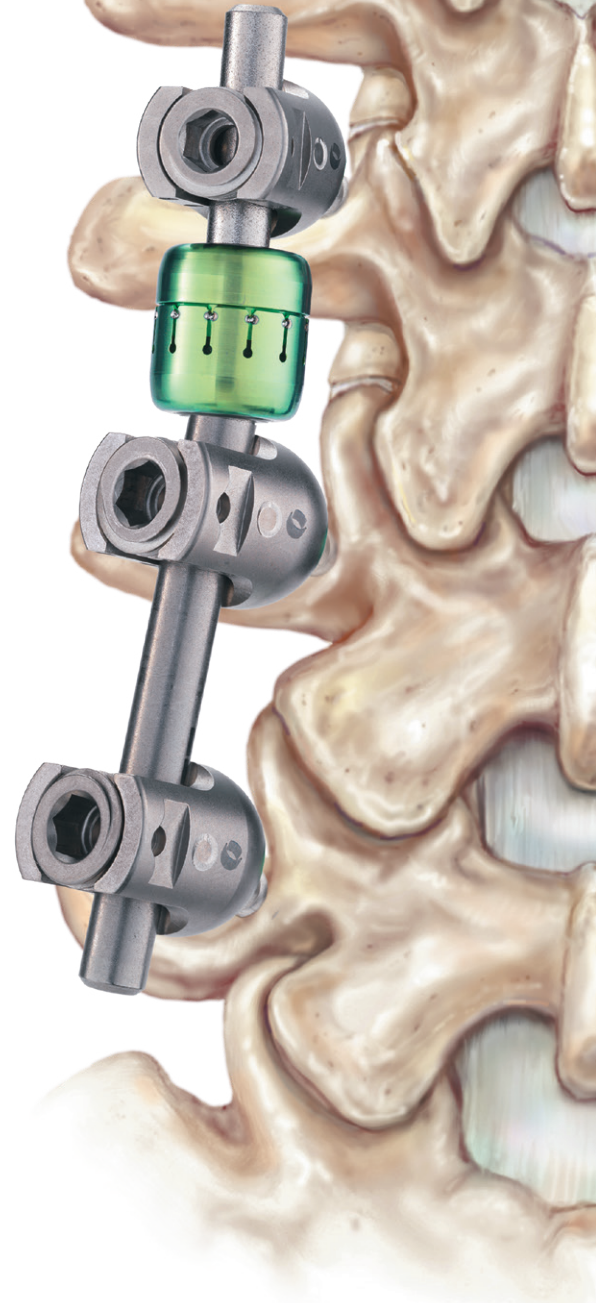
Flex Rod Implant/Flex Rod

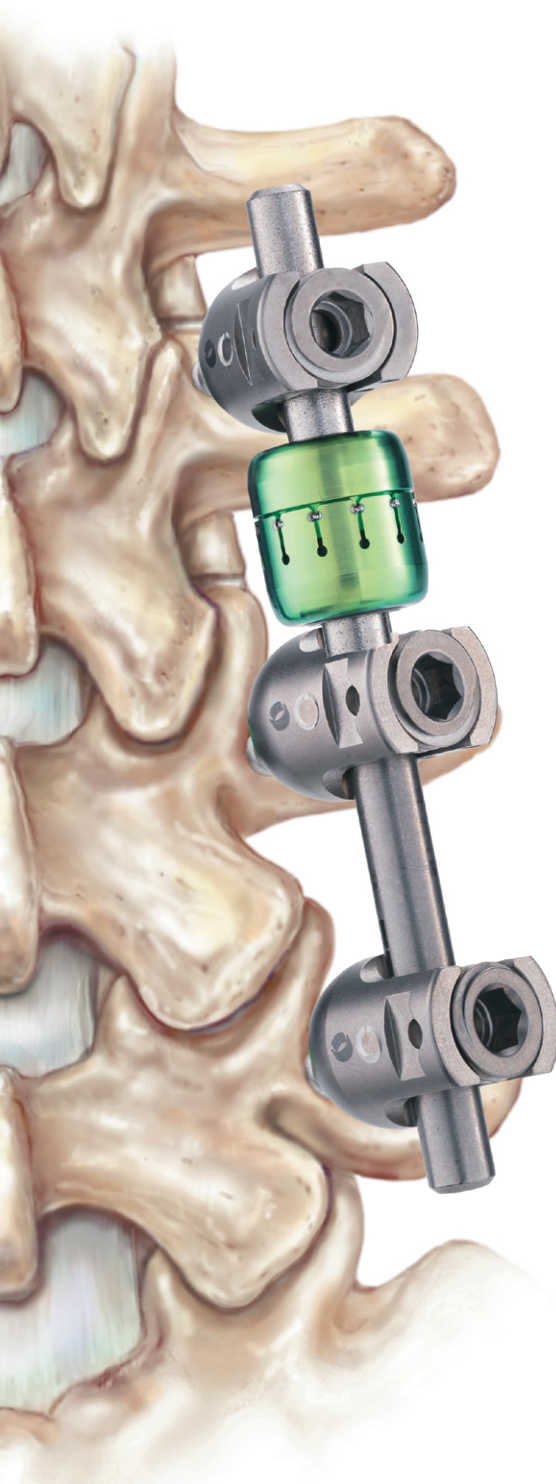


Implant Trial



Insertor/Holder



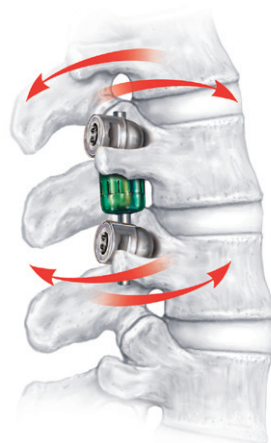


NATURAL MOVEMENT OF THE LUMBAR SPINE

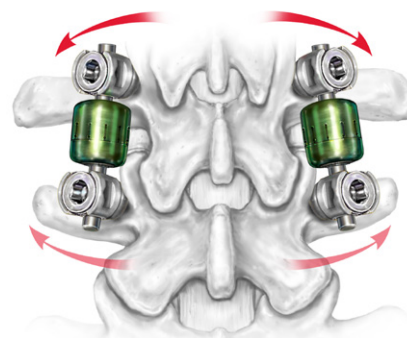
The Orthofix TDX Posterior Dynamic Stabilization System is a posterior dynamic rod allowing natural movements in the treated segments of the lumbar spine. Together with the company's Firebird pedicle screws, the rods can be used for single level motion preservation treatment, or as adjunct to fusion.

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.

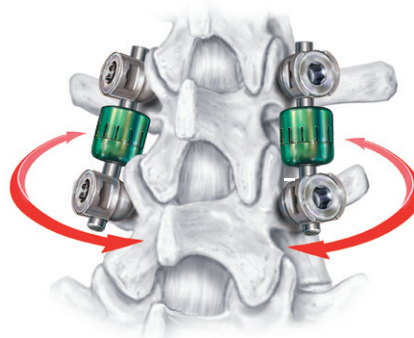
BIOMECHANICAL PERFORMANCE



Flexion-Extension



Lateral Bending



Axial Rotation

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.



Fig. 1a

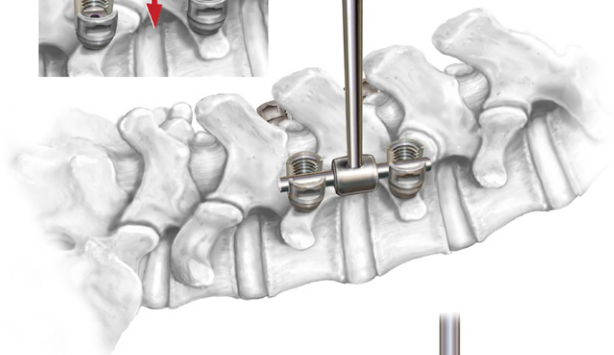


Fig. 1b

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.

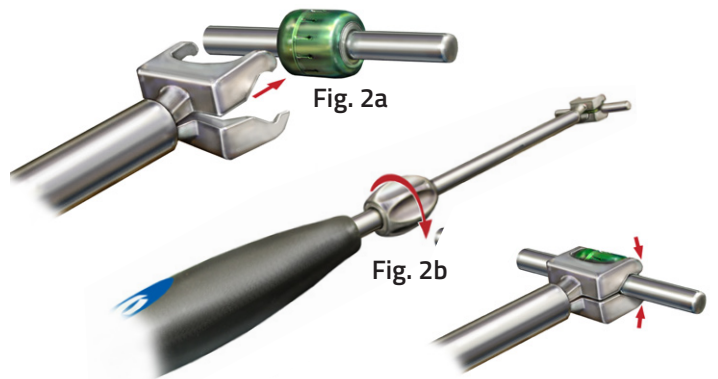


Fig. 2a

Fig. 2b

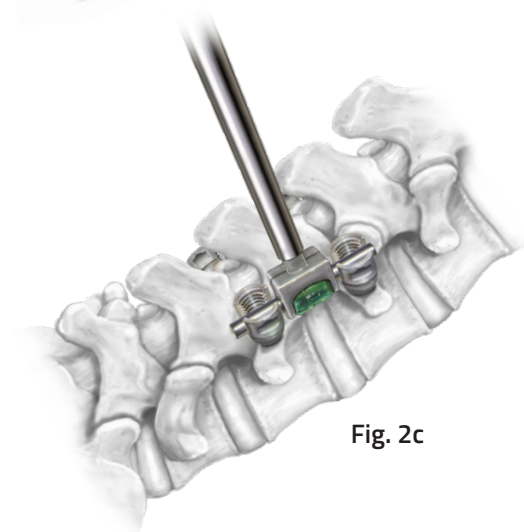


Fig. 2c

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 cannulated set screw counter torque wrench over the multi-axial head and onto the rod, slide the Set Screw Driver 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.

Fig. 3a

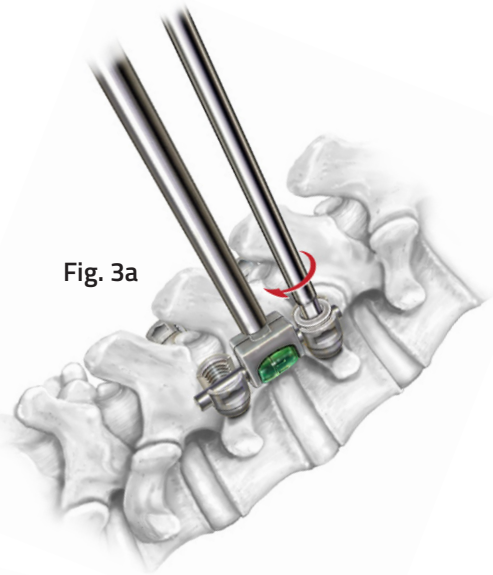
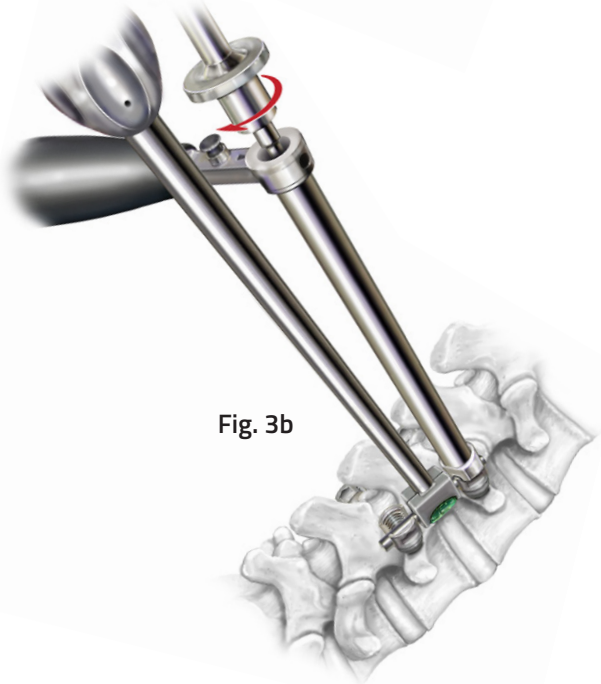


Fig. 3b



REMOVAL PROCEDURE

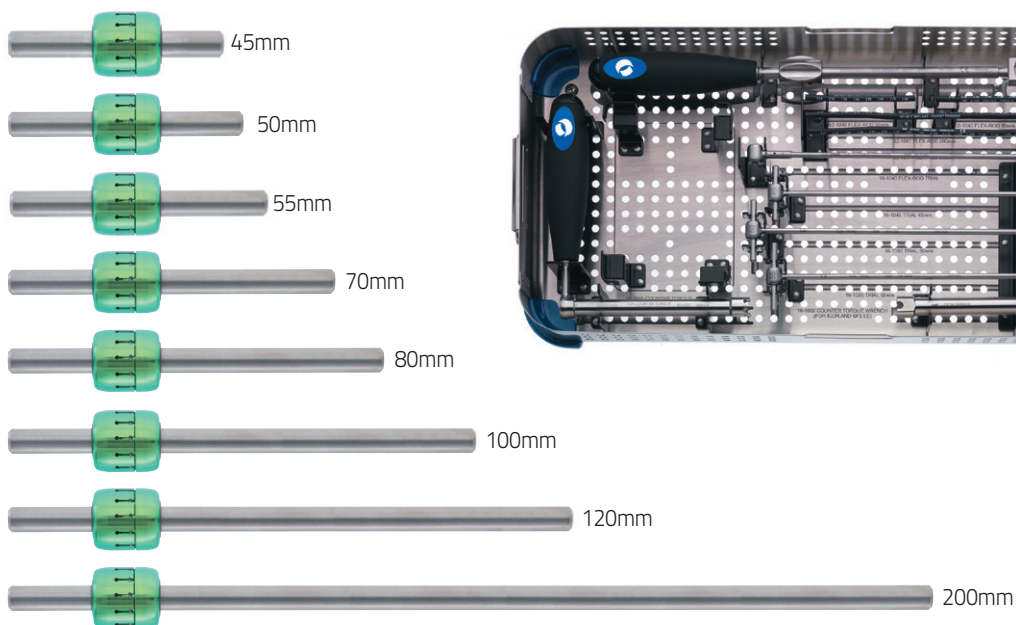
Removal of implants should be performed as outlined in the Firebird Spinal Fixation Operative Technique.

TDX Rods

Part #	Description
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

Part #	Description
16-0001	Instrument Case
16-1000	Insertor/Holder
16-1001	Counter Torque Wrench
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



Please visit [Orthofix.com/IFU](https://www.orthofix.com/IFU) for full information on indications for use, contraindications, warnings, precautions, adverse reactions and sterilization.

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



Orthofix
3451 Plano Parkway
Lewisville, Texas 75056-9453 USA
1.214.937.3199
1.888.298.5700
www.orthofix.com



Medical Device Safety Services (MDSS):
Schiffgraben 41
30175, Hannover
Germany
+49 511 6262 8630
www.mdss.com

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