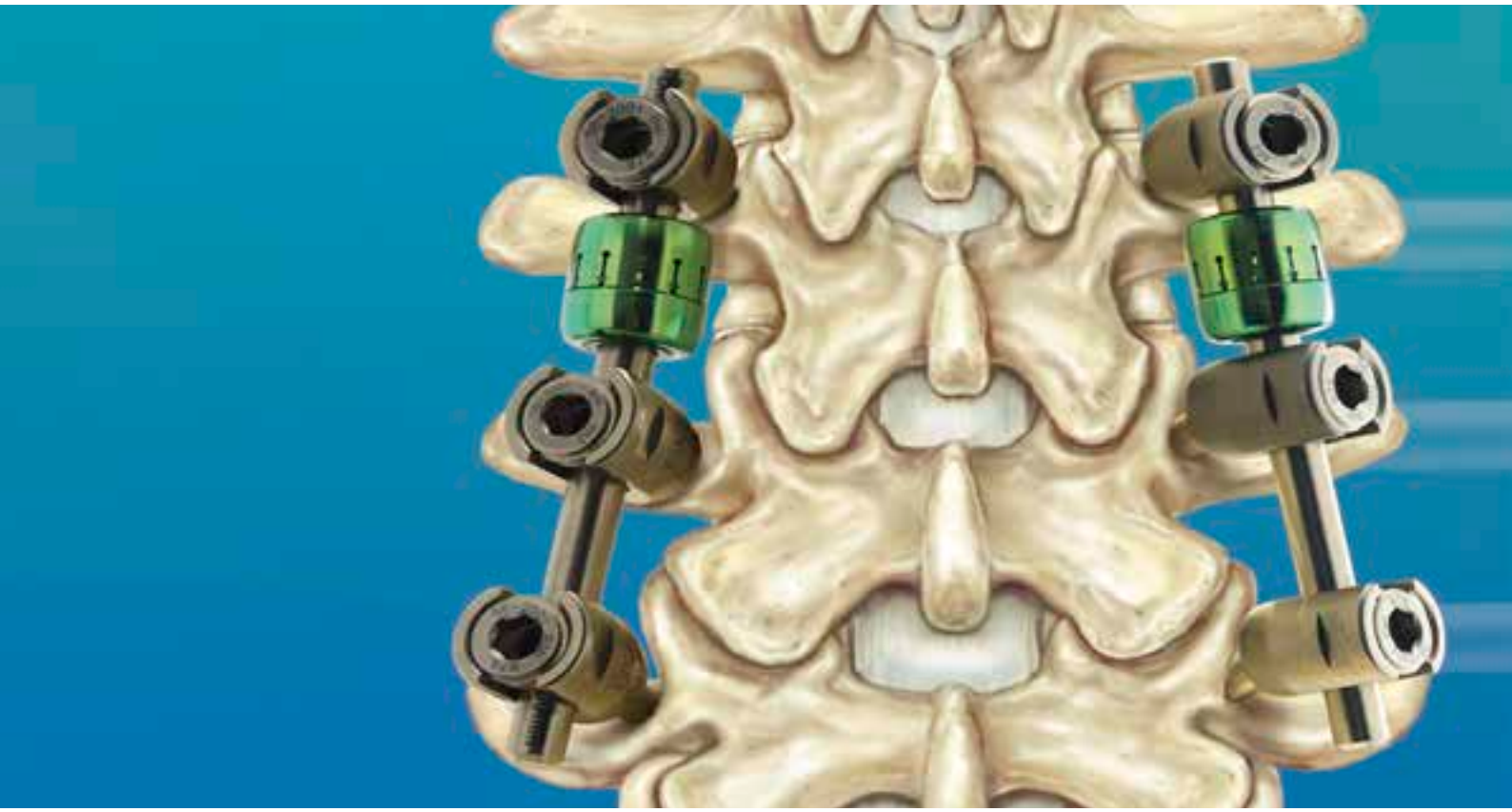
TDX™

Estabilización Dinámica Posterior



TÉCNICA QUIRÚRGICA

MBA®

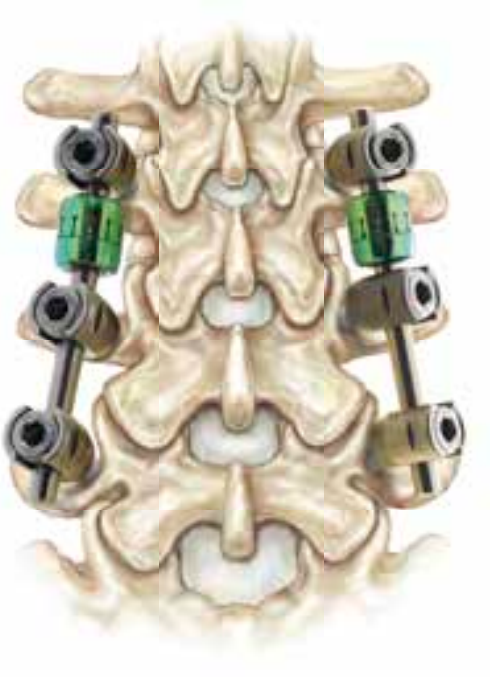
ORTHOFIX®
Spinal Implants

Fabricado por:

ORTHOFIX®
Spine

TDX™

Estabilización Dinámica Posterior



El sistema TDX de estabilización dinámica posterior de Orthofix está basado en una barra dinámica que permite los movimientos naturales dentro del segmento lumbar tratado. Junto con los tornillos pediculares SFS, las barras pueden ser usadas como tratamiento para preservar el movimiento de un nivel vertebral, o como tratamiento complementario a la fusión.

El sistema TDX de estabilización está diseñado para proporcionar la estabilización posterior mientras permite el movimiento natural de la columna lumbar. Como tratamiento de un solo nivel vertebral, las barras TDX permiten la flexión, extensión, rotación y movimientos laterales. En una artrodesis de varios niveles, el sistema TDX favorece la estabilización dinámica en los niveles adyacentes a la vez que proporciona una fijación rígida tradicional.

TDX™

Estabilización Dinámica Posterior

Paso 1

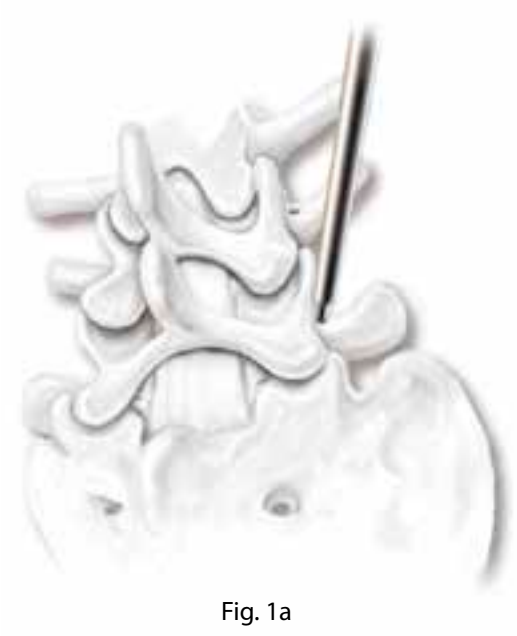


Fig. 1a

Fig. 1b

PREPARACIÓN DEL PEDÍCULO

Emplear un punzón óseo (*Ref. 55-1001*) o una fresa de alta velocidad para crear un orificio guía de entrada en el pedículo (Fig. 1a).

Se emplea la sonda pedicular recta (*Ref. 55-1002*) o curvada (*Ref. 55-1003*), para continuar con la perforación del canal pedicular hasta la profundidad deseada. Las marcas calibradas en las sondas están correlacionadas con las longitudes disponibles de los tornillos (Fig. 1b).

Paso 2

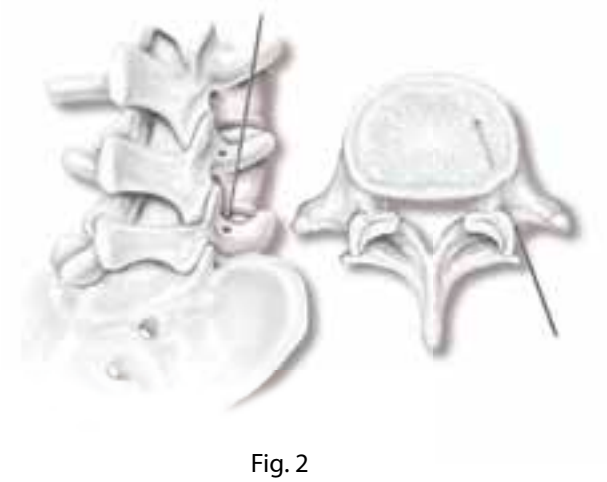


Fig. 2

USO DE LOS PALPADORES

(*Ref. 55-1004 o 55-1005*)

Mediante el palpador recto o curvo se evalúa la condición de la pared cortical del pedículo. El palpador adecuado debe ser empleado con el objeto de asegurar que el pedículo no ha sido atravesado (Fig.2). Este paso debe ser llevado a cabo antes y después del terrajado del pedículo.

Nota

El empleo de la terraja es opcional ya que los tornillos pediculares SFS son autoterrajantes.

Step 3

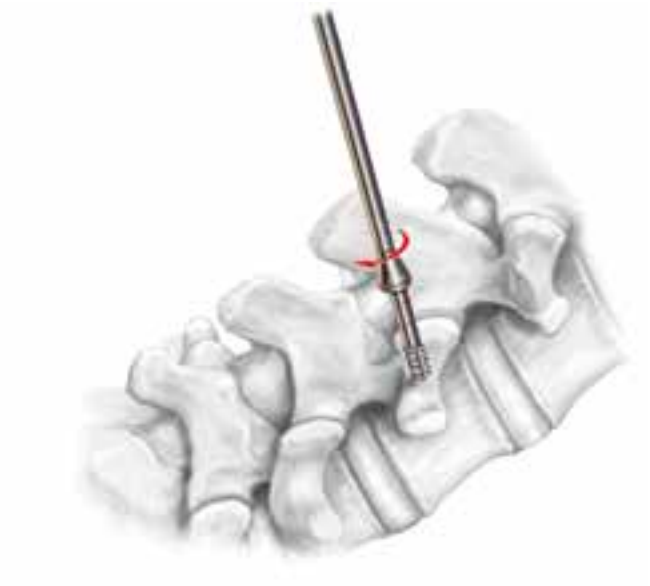


Fig. 3

TERRAJADO

Las terrajas están disponibles desde 5.5 mm hasta 8.5 mm en incrementos de 1mm para facilitar la inserción de los tornillos. Se recomienda terrajar únicamente una parte del total del canal pedicular. Esta práctica reducirá la probabilidad de atravesar la pared pedicular (Fig. 3).

Paso 4

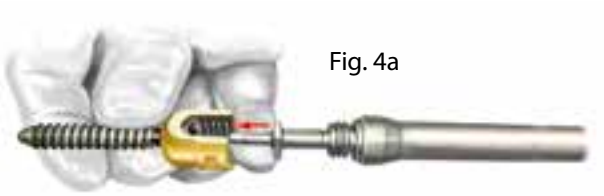


Fig. 4a

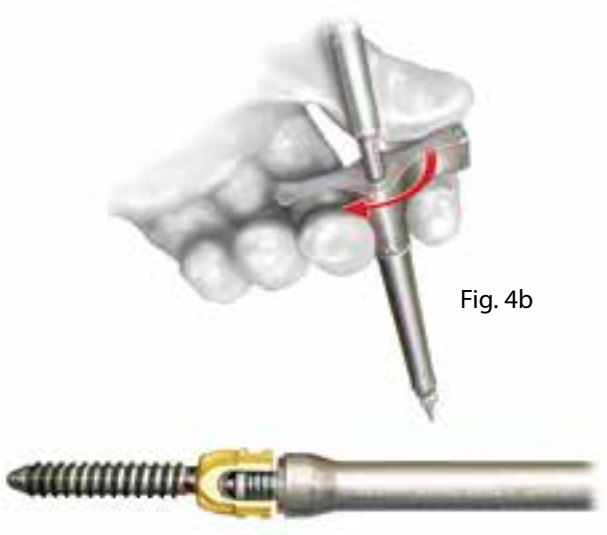


Fig. 4b

COLOCACIÓN DEL IMPLANTE EN EL ATORNILLADOR MULTIAXIAL

Posicione el atornillador de tornillo multiaxial (*Ref. 55-1037*) en la parte ranurada del cuerpo del tornillo pedicular. Inserte la cabeza hexagonal del atornillador multiaxial dentro del cuerpo del tornillo (Fig. 4a).

Gire el atornillador en sentido horario con el fin de ajustar la rosca del lecho del tornillo pedicular al atornillador (Fig. 4b).

Paso 5

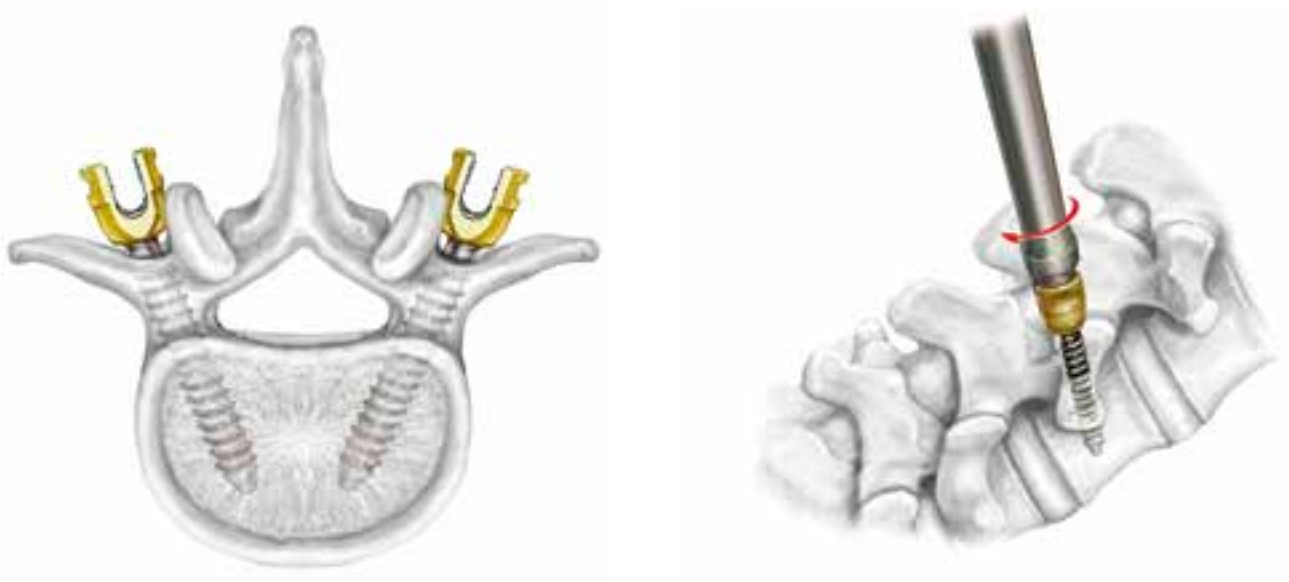


Fig. 5

INSERCIÓN DEL TORNILLO EN EL PEDÍCULO

Introduzca el tornillo multiaxial seleccionado en el pedículo preparado (Fig. 5a). El lecho de los tornillos no debe impactar en las uniones de la facetas ni dañar tejidos blandos en las circundantes. Gire la cabeza del atornillador en sentido antihorario para soltar el tornillo (Fig. 5b).

Paso 6

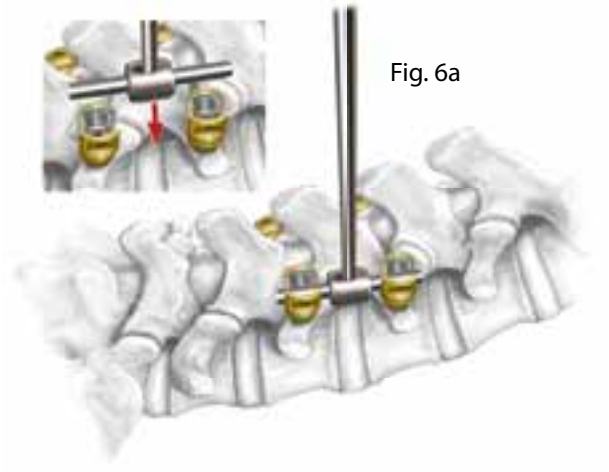


Fig. 6a

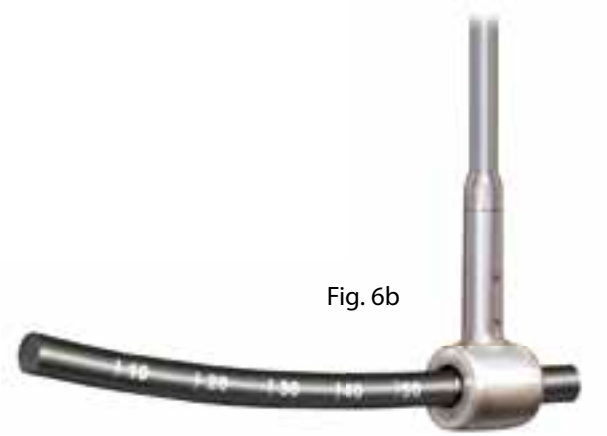


Fig. 6b

IMPLANTE DE PRUEBA

Como ayuda para la selección del tamaño adecuado de la barra, escoja uno de los tamaños de prueba (*Ref. 16-1045, 16-1050 o 16-1055*) e insértelos entre las dos cabezas de los tornillos pediculares (Fig. 6a). Los tamaños de los implantes de prueba son 45, 50 y 55 mm. La geometría de los implantes de prueba coincide de manera exacta con los implantes finales para una óptima evaluación de la talla.

Cuando un implante de mayor tamaño es requerido y necesita un predoblado, se emplea la barra flexible como implante de prueba (*ref. 16-1040*) (Fig. 6b). Inserte dicha barra en el espacio creado a lo largo del canal que une los tornillos pediculares y doble manualmente la barra. La barra flexible puede ser empleada entonces como plantilla para doblar el implante final TDX con el doblador de barra (*Ref. 55-1042*).

Paso 7

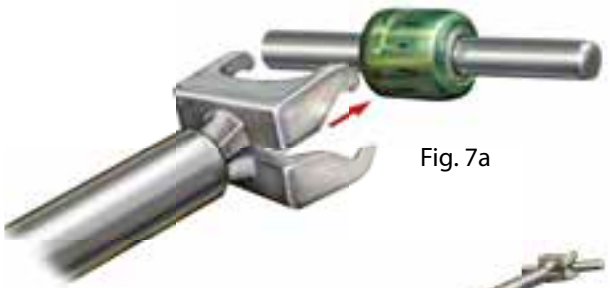


Fig. 7a

Fig. 7b

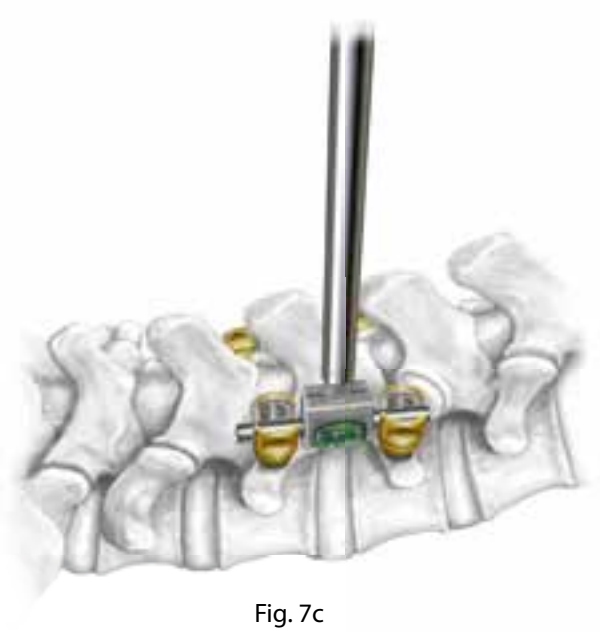


Fig. 7c

INSERCIÓN DEL IMPLANTE

Retire el implante de su caja estéril y colóquelo en el insertador del implante (*Ref. 16-1000*). Gire el insertador en sentido horario para asegurar el implante firmemente (Fig. 7a y Fig. 7b).

Sitúe el implante entre los tornillos pediculares acomodando los segmentos de barra del implante sobre el lecho de los tornillos (Fig. 7c). No retire el insertador del implante ya que éste ayuda a mantener el alineamiento y la orientación de la barra.

Paso 8

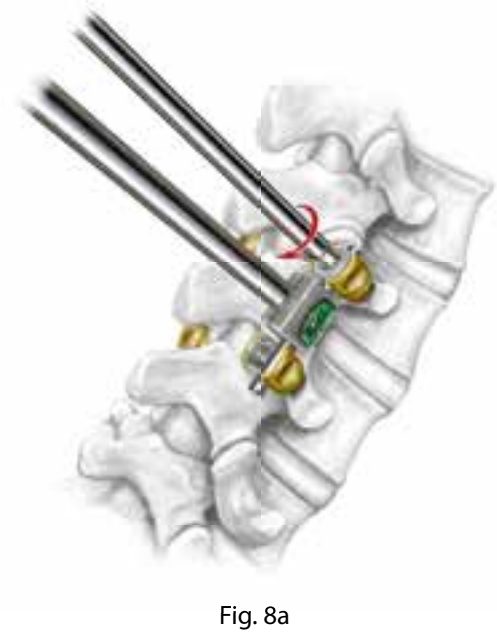


Fig. 8a

Fig. 8b

BLOQUEO DEL IMPLANTE TDX

Emplee el insertador de tornillos de bloqueo (*Ref. 55-1060*) para colocar los tornillos de bloqueo.

Para evitar el tras-roscado, gire el insertador en sentido horario hasta que ambas roscas se encuentren alineadas. Una vez conseguido, introduzca el tornillo de bloqueo en el lecho (Fig. 8a).

Introduzca la llave canulada de contrafuerza sobre la cabeza multiaxial del tornillo y la barra. Introduzca a continuación el atornillador a través de la llave de contrafuerza (*Ref. 55-1065*) y encájela en el tornillo de bloqueo (Fig. 8b).

Para terminar de bloquear el montaje, aplique una torsión de 100 libras-pulgada a cada tornillo de bloqueo con la llave dinamométrica con mango en T (*Ref. 55-1068*).

Finalmente, retire el insertador de implante TDX.

descripción y números de referencia

TDX RODS

16-2045	TDX rod, 45 mm
16-2050	TDX rod, 50 mm
16-2055	TDX rod, 55 mm
16-2070	TDX rod, 70 mm
16-2080	TDX rod, 80 mm
16-2200	TDX rod, 200 mm

TDX INSTRUMENTS

16-0001	Instrument case
16-1000	Inserter/Holder
16-1001	Counter torque wrench-SFS
16-1002	Adjustable counter torque wrench
16-1040	Flex rod implant trial
16-1045	45 mm implant trial
16-1050	50 mm implant trial
16-1055	55 mm implant trial
52-1040	90 mm flexible trial rod
52-1041	200 mm flexible trial rod

SPECIFIC INSTRUMENTS

55-1001	Bone awl
55-1002	Bone probe
55-1003	Curved bone probe
55-1004	Straight Sounder
55-1005	Curved Sounder
57-0011	3.5 mm bone tap
57-0010	4.5 mm bone tap
55-1025	5.5 mm bone tap
55-1026	6.5 mm bone tap
55-1027	7.5 mm bone tap
55-1028	8.5 mm bone tap
55-1037	Multi-axial screw driver, wing
55-1060	Set screw driver/holder
55-1062	Set screw Intermediate driver
55-1065	Deflection beam torque wrench (not ratchet)
55-1068	Torque T-Handle 100 in-lbs

TDX™

Estabilización Dinámica Posterior

Description: The Orthofix 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 Orthofix Spinal Fixation System consists of an assortment of screws, hooks, rods, spacers, staples, washers, dominos, lateral offsets, and cross connectors. The Orthofix TDX Stabilization System, which can be used with non-reduction style pedicle screws and cross connectors, is a sterile, single-use component that allows the surgeon to build a spinal implant construct. The TDX Stabilization System consists of polyurethane core which is secured in an implant grade titanium housing. The Orthofix Spinal Fixation System titanium implants are not compatible with components or metal from any other manufacturer's system.

Levels of Use: The Orthofix Spinal Fixation System is intended for non-cervical use in the spine. When used as a non-pedicle anterolateral fixation system it may be used from levels T1 to S1. When used with pedicle screw fixation, the Orthofix 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-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	Applicability
The Orthofix Spinal Fixation System is intended for non-cervical use in the spine. The Orthofix Spinal Fixation System, when used for pedicle screw fixation, is intended only for patients: a) Having severe spondylolisthesis (Grades 3 and 4) at the L5-S1 joint; b) Who are receiving fusion using autogenous bone graft only; c) Who are having the device fixed or attached to the lumbar and sacral spine (L3 and below); and d) Who are having the device removed after the development of a solid fusion mass.	Pedicle Screws (non-reduction style), Rods, Cross Connectors, Dominos, Lateral Offsets, and Spacers.
The Orthofix Spinal Fixation System, when used as a pedicle screw system in skeletally mature patients, is intended to provide immobilization and stabilization of spinal segments, as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine: a) Degenerative spondylolisthesis with objective evidence of neurologic impairment; b) Fracture; c) Dislocation; d) Scoliosis; e) Kyphosis; f) Spinal tumor; and g) Failed previous fusion (pseudoarthrosis).	Pedicle Screws (non-reduction style), Rods, Cross Connectors, Dominos, Lateral Offsets, and Spacers.

descripción y números de referencia

The Orthofix Spinal Fixation System, when used for anterolateral non-pedicle screw fixation to the non-cervical spine, is intended for the following indications: a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies); b) Spondylolisthesis; c) Spinal stenosis; d) Spinal deformities (i.e., scoliosis, kyphosis, and/or lordosis); e) Tumor; f) Pseudoarthrosis; g) Failed previous fusion; and h) Trauma (i.e., fracture or dislocation).	Screws (non-reduction style), Rods, Cross Connectors, Dominos, Lateral Offsets, Spacers, Staples, and Washers.
The Orthofix Spinal Fixation System, when used for posterior non-pedicle screw fixation system of the non-cervical spine, is intended for the following indications: a) Degenerative disc disease (as defined as back pain of discogenic origin with degenerative disc confirmed by history and radiographic studies); b) Spondylolisthesis; c) Spinal stenosis; d) Spinal deformities (i.e., scoliosis, kyphosis, lordosis); e) Tumor; f) Pseudoarthrosis; g) Failed previous fusion; and h) Trauma (i.e., fracture or dislocation).	Hooks, Rods, Cross Connectors, and Dominos.
When used as a pedicle screw fixation system in skeletally mature patients, the TDX Stabilization System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion in the treatment of the following acute and chronic instabilities for deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, kyphosis, and failed previous fusion (pseudoarthrosis). In addition, when used as a pedicle screw fixation system, the TDX Stabilization System is indicated for use in patients: • Who are receiving fusions with autogenous graft only; • Who are having the device fi xed or attached to the lumbar or sacral spine; and • Who are having the device removed after the development of a solid fusion mass	TDX Stabilization System

Note: For all of these indications, 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 Stabilization System, 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.

descripción y números de referencia

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) When used as a pedicle screw implant system, the 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 fusion 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 .

7) Non-sterile; the screws, hooks, dominos, lateral offsets, spacers, staples, washers, locking nuts, cross connectors, and instruments are sold non-sterile, and therefore must be sterilized before use.

8) The TDX Stabilization System is sold sterile, and therefore should not be resterilized.

9) To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used.

10) Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.

11) Excessive torque applied to the screws may strip the threads in the bone.

12) DO NOT REUSE IMPLANTS. Discard used, damaged, or otherwise suspect implants.

13) 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.

14) 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.

15) The safety and effectiveness of this device for the indication of spinal stabilization without fusion have not been established.

16) Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not sterilize single-use implants that come in contact with body fluids.

Instructions for Use: See actual package insert for Instructions for Use.

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