OPERATIVE TECHNIQUE

SFS

SPINAL FIXATION SYSTEM

ORTHOFIX®

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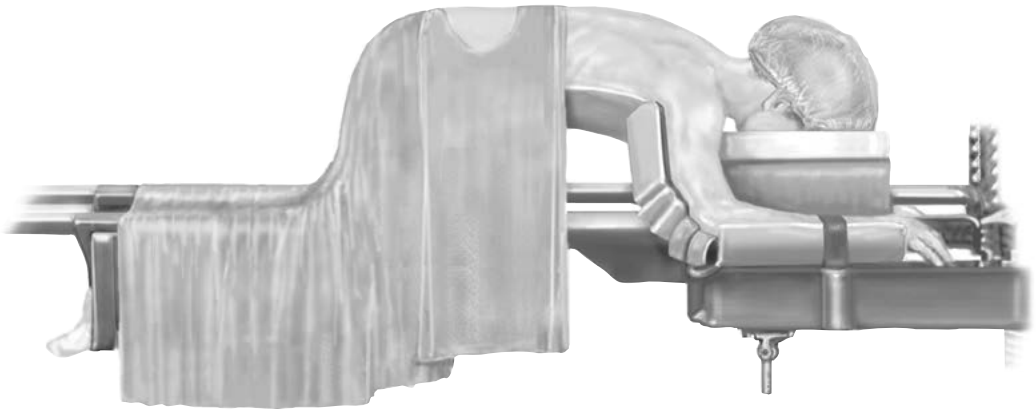
The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Please see Instructions for Use for the complete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

INTRODUCTION

The SFS System provides simple, reliable and comprehensive stabilization solutions for spinal fixation. Its patented innovations enable surgeons to work efficiently and with confidence.

The pedicle screws provide a full 42° multi-axial range of motion that, in conjunction with their uniquely tapered heads, are more accommodating to variables in patient anatomy/pathology. This simplifies screw placement and helps reduce the need for rod bending. Additionally, the fixation screw utilizes a unique buttress thread design that helps minimize the potential for misalignment or cross-threading.



1. PATIENT POSITIONING

The patient is placed on the operating room table in a prone position.

If you place the patient on a frame with the hips extended, lumbar lordosis will increase. Radiographic imaging or quality X-rays are used intraoperatively. The patient's position should be checked radiographically (C-arm or X-ray) to determine the direction of the pedicle relative to the horizontal plane.

Fig. 2a

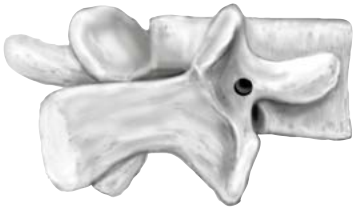
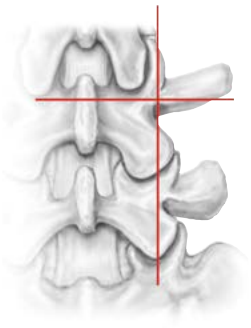


Fig. 2b



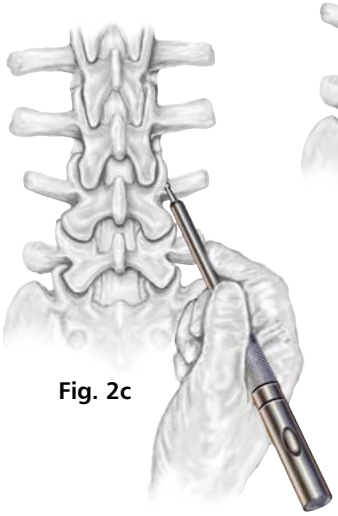


Fig. 2c

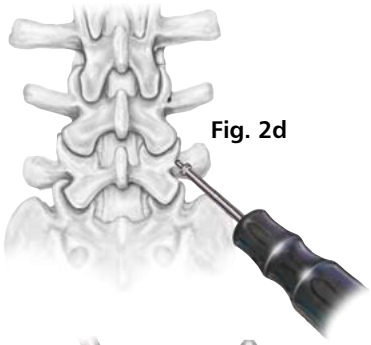


Fig. 2d

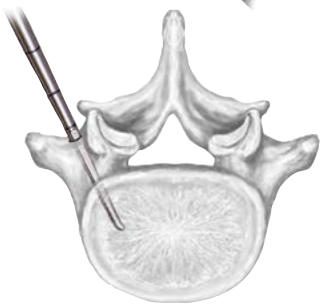


Fig. 2e

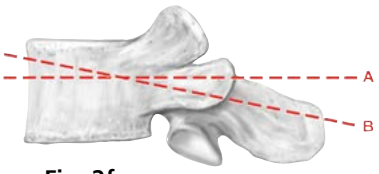


Fig. 2f

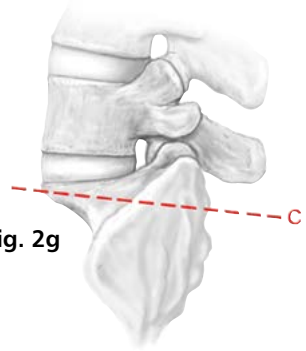


Fig. 2g

2. PEDICLE PREPARATION

Step 2a

Identification of the Pedicles

Proper entry point to the lumbar pedicle is located at the convergent point of three anatomic structures. The middle of the transverse process, the superior facet and the pars interarticularis converge over the dorsal portion of the pedicle **(Fig. 2a)**. This starting point can also be identified at the lateral border of the superior articular facet where it intersects with a line drawn through the middle of the transverse process. **(Fig. 2b)**. A burr or ronguer may be used to clear away the hard cortical bone at the junction of the facet and transverse process, thereby exposing the cancellous portion of the pedicle **(Fig. 2c)**.

The starting point in the sacral pedicles is different from the lumbar pedicles due to the lack of transverse processes and the presence of the sacral ala. The size and configuration of the S1 pedicle allows the surgeon more flexibility in positioning the screw within the sacrum. The S1 pedicle is caudal and slightly lateral to the superior articular process; therefore, the entry point should be in the most caudal portion of the pedicle.

Step 2b

Preparation of the Pedicle Canal

Note that the sagittal plane inclination of the probe should be parallel to the adjacent vertebral endplate **(Fig. 2d)**. At the most cephalad vertebrae included in the construct, the starting point should be at the caudal portion of the pedicle and the probe should be angled in a cephalad direction **(Fig. 2e)**. This maneuver will place the pedicle screw entry hole below and away from the unfused superior facet joint **(Fig. 2f)**.

The S1 sacral entry point should be placed at the caudal portion of the S1 pedicle. The probe is then angled 25 to 30 degrees medially and cephalad thus directing the probe tip toward the sacral endplate. The caudal entry point and the cephalad angulation of the probe will ensure that the S1 screw will not interfere with the placement of the adjacent L5 screw **(Fig. 2g)**.

NOTE: Most surgeons will place S1 screws bicortical (i.e. just through the anterior cortex of S1).

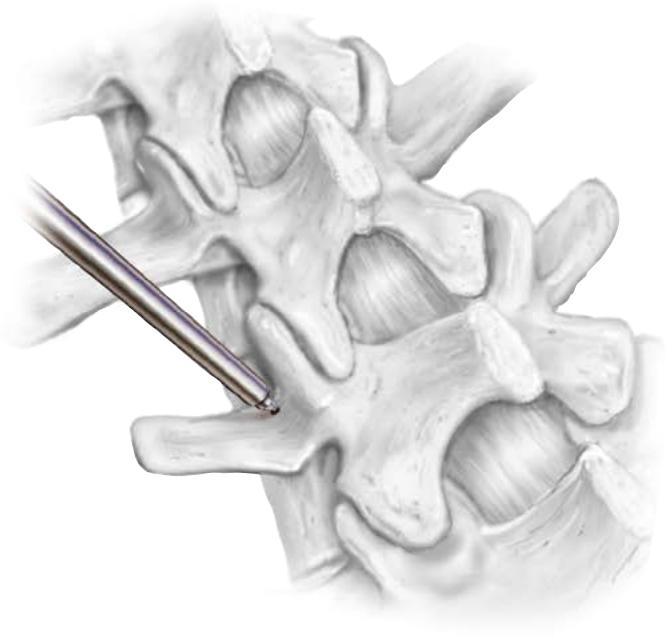


Fig. 3

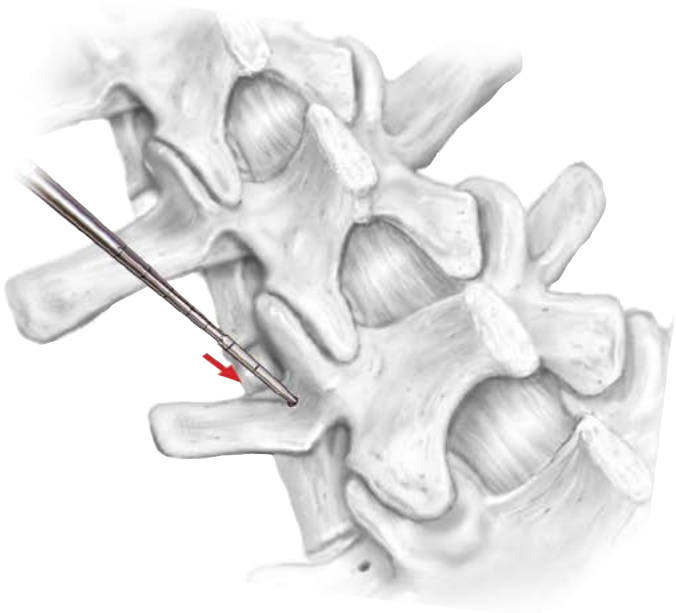


Fig. 4

3. BONE AWL

(57-0042) 4.5mm Bone Awl
(55-1001) Bone Awl

Penetrate the cortex of the bone with the bone awl to create a pilot hole at the pedicle entry point.

4. BONE PROBE

(57-0030) Bone Probe Curved 4.5mm
(57-0032) Bone Probe Straight 4.5mm
(55-1002) Bone Probe Straight
(55-1003) Bone Probe Curved

Use the straight or curved bone probe to elongate the hole to the desired depth in the pedicle canal, staying within the pedicle walls.

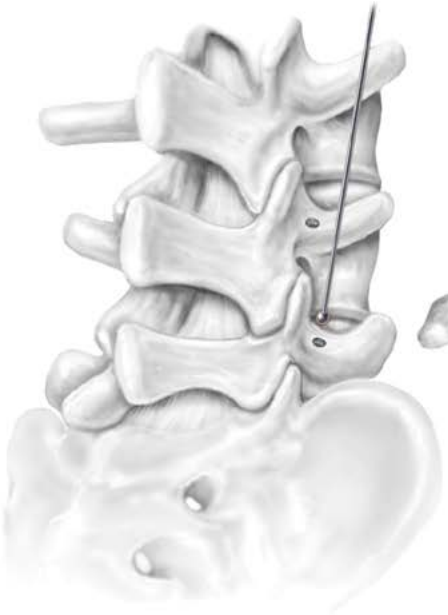


Fig. 5a

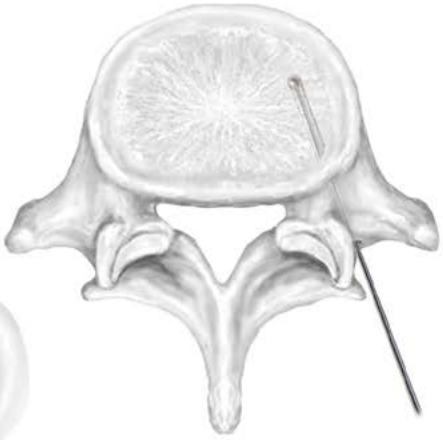


Fig. 5b

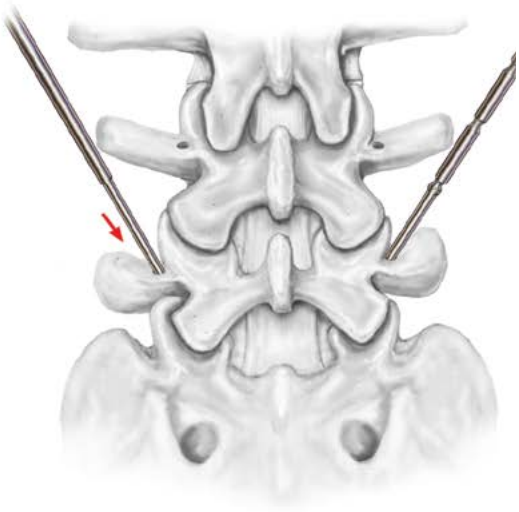


Fig. 6

5. SOUNDER

(55-1004/55-1005)

Use the straight or curved sounder to evaluate the integrity of the cortical wall of the pedicle. Choose the appropriate tip and externally or internally palpate the wall or canal of the pedicle to ensure the wall is not perforated.

6. (OPTIONAL) X-RAY MARKERS

(55-1006/55-1007)

Use the right and left x-ray markers to confirm pedicle trajectory under fluoroscopy prior to pedicle screw insertion.

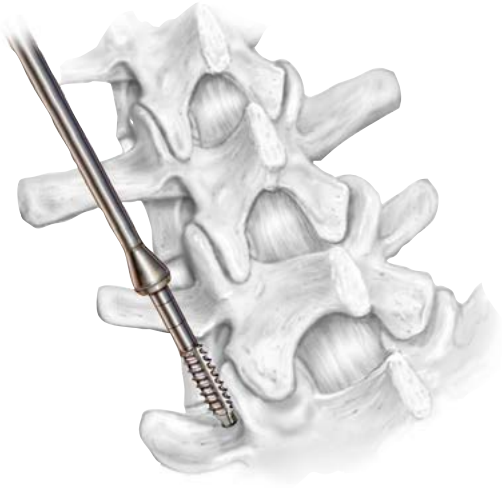


Fig. 7

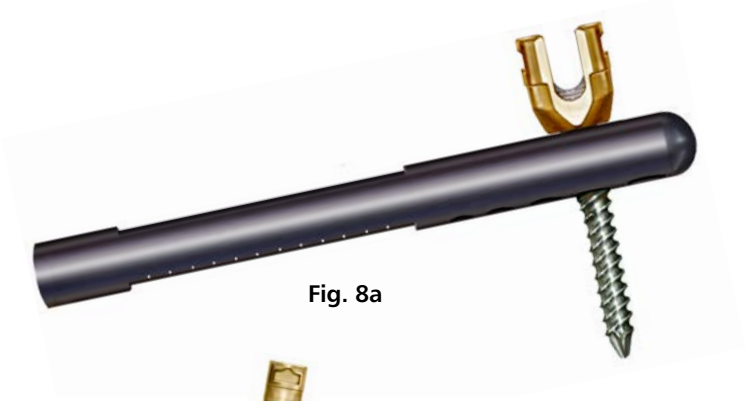


Fig. 8a

Fig. 8b

7. (OPTIONAL) BONE TAP

(57-0011/57-0010) 3.5mm-4.5mm
(55-1025 thru 55-1028) 5.5mm-8.5mm

Tap to the appropriate depth based on the length of the pedicle screw to be implanted for optimized screw purchase, using the millimeter markings on either the tap or the bone probe as a guide.

NOTE: For standard tip screws only. Self-tapping screws do not require the use of a tap to facilitate screw insertion.

8. SCREW SELECTION

Screw Template (55-1050)

Use the screw template to verify screw diameter **(Fig. 8a)** and length of multi/mono-axial screw length **(Fig. 8b)** prior to insertion.

Implant and driver fully assembled

Fig. 9a

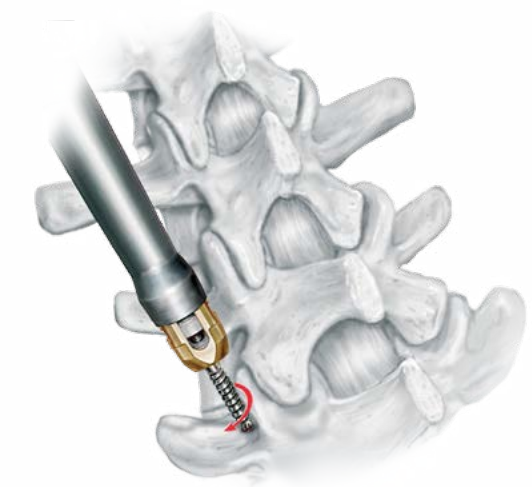


Fig. 9b

9. SCREW INSERTION

Step 9a - Multi-Axial and Mono-Axial Screws

Multi-Axial Screw Driver Nut (55-1036)
Wing (55-1037) or
Mono-Axial Screw Driver (55-1035)

Insert the appropriate driver to a ratcheting handle. Set the handle to neutral or reverse position. Thread the driver into the screw by rotating the driver knob clockwise. **Rotate the knob… ratcheting handle counter clockwise to obtain rigid fixation.** Set the ratcheting handle into forward position to facilitate screw placement. **(Fig. 9a and Fig. 9b)**

NOTE: Insert the screw into the prepared pedicle until it is positioned to the correct level. The screw should extend approximately 50% to 80% in the vertebral body.

To disengage the screw driver from the screw body, turn the knob counter clockwise until the screw releases from the tip. Proceed to **Screw Adjustment (Step 10)**.

NOTE: If screws are placed too deeply, full range of motion may be lost. To regain mobility, turn the screw counter clockwise with the driver or adjustment driver until mobility is reestablished.

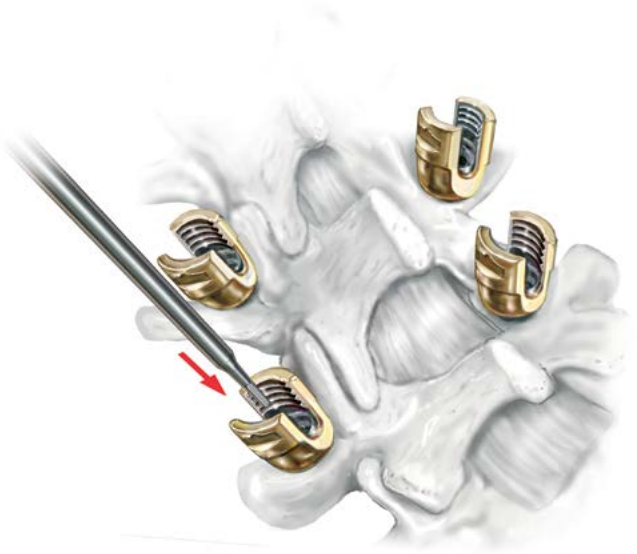


Fig. 10

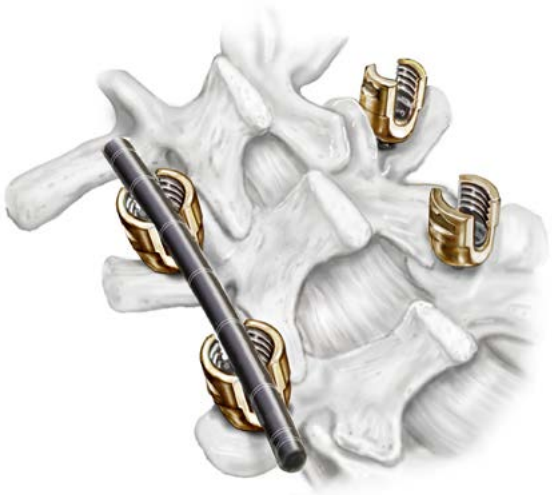


Fig. 11a

10. SCREW ADJUSTMENT

Multi-Axial Adjustment Driver (55-1063)

Insert adjustment driver into a ratcheting handle. Set the handle to neutral position. Insert driver tip into multi-axial screw body. Rotate handle until desired sagittal height of the pedicle screw has been reached prior to rod insertion.

11. ROD PREPARATION

Step 11a

Rod Template

Determine the rod contour and length required using the trial rod. (55-1055 thru 55-1057)

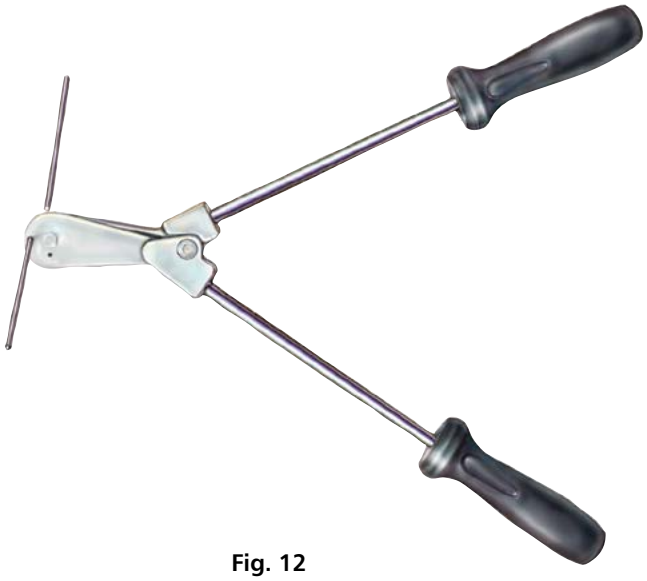


Fig. 12

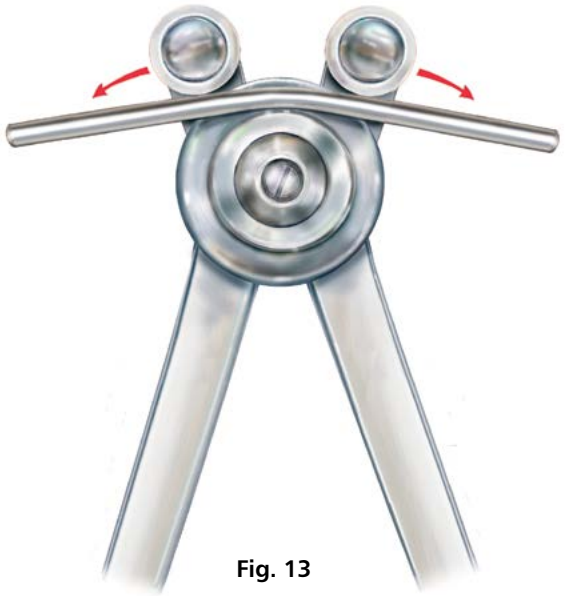


Fig. 13

12. ROD CUTTING

Pin Cutter (55-1041)
Once the correct length is established, use the rod cutter to cut rod to the desired length referencing the rod template as a guide.**(Fig. 12)**

13. ROD CONTOURING

Rod Bender (55-1042)

Utilizing the rod bender, create the correct contour, referencing the rod template as a guide.**(Fig. 13)**

WARNING: Excessive or repeated bending of rods may reduce strength and result in construct failure.

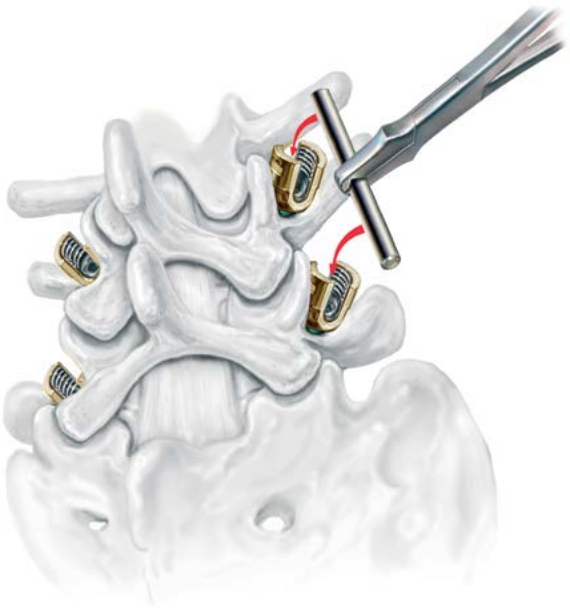


Fig. 14

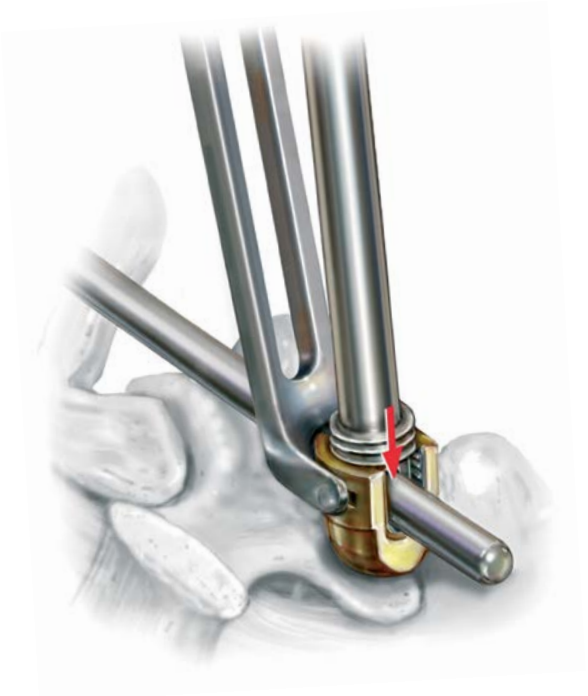


Fig. 15a

14. ROD INSERTION

Rod Holder (55-1043)

Orient the screws so that the screw bodies are in the longitudinal plane. Once positioning is achieved, use the rod holder to place the rod in the screw bodies.

15. (OPTIONAL) ROD REDUCTION

Step 15a

Rocker (55-1044)

Attach rocker to pedicle screw body and lever rod until seated in the pedicle screw (Proceed to Step 16).

Step 15b

Rod Pusher (not shown) (55-1049)

Position rod pusher tip on rod and apply axial force until rod is seated in pedicle screw body (Proceed to Step 16).

Step 15c

Linear Rod Reducer (not shown) (55-1048)

Position rod reducer tip over rod and attach to pedicle screw body. Rotate the knob until the rod is seated in pedicle screw body (Proceed to Step 16).

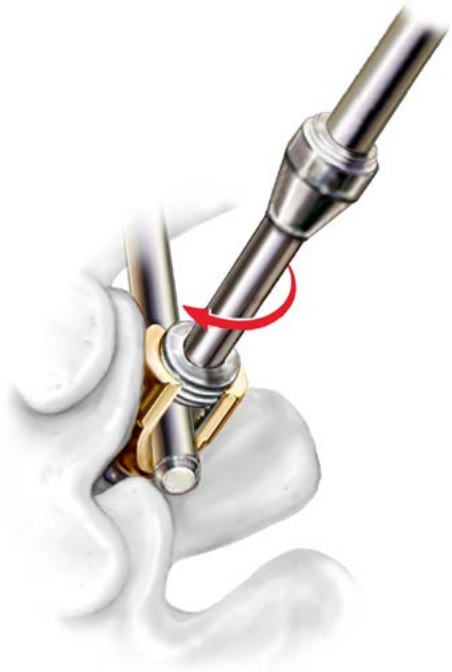


Fig. 16

16. ROD FIXATION

Set Screw Driver/Holder (55-1060)

Rotate the set screw counter clockwise until the set screw properly seats into the mating thread. Turn the driver clockwise to thread the set screw into the pedicle screw body and preliminarily fixate the rod.

17. (OPTIONAL) ROD MANIPULATION

Option A

In-situ Rod Benders (55-1046 right, 55-1047 left)

Position the in-situ rod benders on rod. Gently pull rod benders apart or push the benders towards each other to facilitate bending the rod into the desired configuration.

Option B

Locking Pliers (55-1045)

Attach locking pliers to rod and apply rotational force to adjust rod orientation prior to fixation.

Option C

Distractor (55-1070)

Compressor (55-1071)

For compression, after all set screws have been preliminarily fixated to the rod, loosen the set screw of the pedicle screw to be adjusted using the set screw driver. Compress against the appropriate heads and re-tighten the set screw when desired compression has been achieved.

For distraction, follow the same process as in compression but use the distractor to achieve desired distraction. Similarly, re-tighten the set screw when desired distraction has been achieved.

Fig. 18a

Fig. 18b

18. FINAL TIGHTENING

Self-Center Counter Torque Wrench (55-1069)

Self-Centering Set Screw Driver (55-1064 used with 55-1069)

Torque T-Handle (55-1068)

Position the counter Torque T-Handle wrench over the pedicle screw and rod (55-1067 not shown). Place the set screw driver through the cannulation of the counter torque wrench and into the hex of the set screw. Turn the Torque T-Handle clockwise to tighten the set screw to 100 in-lbs. **(Fig. 18a)** The handle will reach its maximum torque and release at 100 in-lbs.

(OPTIONAL) CROSS CONNECTIONS

Cross-Connector Templates (55-1095 – 55-1099 and 57-1015 – 57-1023)

Cross-Connector Benders, Right (55-1073) and Left (55-1072)

Cross-Connector Torque Limiting Driver (55-1089)

The appropriate size cross-connector is determined with the cross-connector templates. The appropriate multi-axial or fixed cross-connector is chosen and placed between the two rods in the construct. If contouring of the multi-axial cross-connector is needed, use the cross-connector benders.

Once the correct position of the cross-connector is established on the rods, use the cross-connector driver to advance each of the set screws and fixate the cross-connectors onto the rods applying 13 in-lbs of torque. It is recommended to alternate tightening from side to side in order to get a uniform closure onto both rods.

IMPLANT REMOVAL

Self-Centering Set Screw Driver (55-1064)

Self-Center Counter Torque Wrench (55-1069)

Multi-axial Adjustment Driver (55-1063)

Mono-axial Screw Driver (55-1035)

In order to remove the multi-axial screws, fully seat the set screw driver securely into the set screw and turn counter clockwise to loosen the set screws. Use of counter torque wrench is recommended to avoid damage to the pedicle. **(Fig. 18b)** Carefully remove all set screws. The multi-axial adjustment driver can be utilized to remove the screw assemblies.

In order to remove the mono-axial screw, fully seat the set screw driver securely into the set screw and turn counter clockwise to loosen the set screw. The mono-axial set screw driver can be utilized to remove the screws.

Instruments

Part #	Description
52-1035	F-F Implant Inserter
55-1001	Bone Awl
55-1002	Straight Bone Probe
55-1003	Curved Bone Probe
55-1004	Straight Sounder
55-1005	Curved Sounder
55-1006	X-Ray Marker, Right
55-1007	X-Ray Marker, Left
55-1025	5.5mm Bone Tap
55-1026	6.5mm Bone Tap
55-1027	7.5mm Bone Tap
55-1028	8.5mm Bone Tap
55-1030	Ratcheting Handle
55-1031	Ratcheting T-Handle
55-1035	Mono-Axial Screw Driver
55-1036	Multi-Axial Screw Driver, Nut
55-1037	Multi-Axial Screw Driver, Wing
55-1041	Pin Cutter
55-1042	Rod Bender
55-1043	Rod Holder
55-1044	Rocker
55-1045	Locking Pliers
55-1046	In-Situ Rod Bender, Right
55-1047	In-Situ Rod Bender, Left
55-1048	Linear Rod Reducer
55-1049	Rod Pusher
55-1050	Screw Sizing Template
55-1060	Set Screw Driver/Holder
55-1061	Set Screw Driver (w/ 55-1065)
55-1062	Set Screw Intermediate Driver
55-1063	Multi-Axial Adjustment Driver
55-1064	Self-Centering Set Screw Driver (Only use with 55-1069)
55-1065	Deflection Beam Torque Wrench (non-ratchet)
55-1066	Set Screw Counter Torque Wrench
55-1067	Torque T-Handle 120 in-lbs
55-1068	Torque T-Handle 100 in-lbs
55-1069	Self-Center Counter Torque Wrench
55-1070	Hook Spreader (Distractor)
55-1071	Compressor
55-1072	Cross Connector Bender, Left
55-1073	Cross Connector Bender, Right
55-1089	Cross Connector Torque Limiting Driver/13-in-lbs
55-1090	SFS Case #1
55-1091	SFS Case #2

Instruments (Cont.)

Part #	Description
55-1093	SFS Case #3
55-1095	Cross Conn. Template 30 & 35mm
55-1096	Cross Conn. Template 40 & 45mm
55-1097	Cross Conn. Template 50 & 55mm
55-1098	Cross Conn. Template 60 & 65mm
55-1099	Cross Conn. Template 70, 75 & 80mm
55-1150	Staple Holder/Impactor

Disposable Instruments

Part #	Description
55-1055	Trial Rod 90mm
55-1056	Trial Rod 200mm
55-1057	Trial Rod 450mm

Reduction Screw Instruments

Part #	Description
59-0100	Anti-Splay Tool
59-0200	Scalloped Anti-Splay Tool
59-0300	Reduction Screw Head Adjuster
59-0400	Tab Removal Tool
59-1035	Mono-Axial Reduction Screw Driver
59-1037	Multi-Axial Reduction Screw Driver
59-1090	SFS Reduction Screw Sterilization Case

Hook Instruments

Part #	Description
57-0001	Reg Hook Holder, Straight
57-0003	Reg Hook Holder, Angled
57-0005	Lateral Hook Holder, Straight
57-0007	Lateral Hook Holder, Angled
57-0009	Rod Rocker
57-0020	Rigid Hook Holder
57-0022	Hook Linear Rod Reducer (Compressor)
57-0023	Hook Pusher
57-0025	Hook, Lateral Rod Reducer
57-0026	Lever, Hook Lateral Rod Reducer (Compressor)
57-0027	Set Screw Driver (Spline Drive)
57-0035	Transverse Process Elevator
57-0037	Pedicle Elevator
57-0040	Lamina Elevator
57-0045	Set Screw Driver/Holder
57-0047	Hook Set Screw Torque T-Handle/80 in lbs
57-0050	Combination Wrench, 5mm
57-0051	Rod Clamp
57-1015	Cross Conn Template - 15 & 17mm
57-1019	Cross Conn Template - 19 & 21mm
57-1023	Cross Conn Template - 23 & 25mm
57-1090	Hook Instrument Case

4.5mm Instruments

Part #	Description
57-0010	4.5mm Bone Tap w/35mm Stop
57-0011	3.5mm Bone Tap w/30mm Stop
57-0030	Bone Probe Curved 4.5mm
57-0032	Bone Probe Straight 4.5mm
57-0042	Bone Awl
55-1093	Ancillary Instrument Case #3, Deformity

Standard Multi-Axial Screws

Part #	Description
56-3425	4.5mm x 25mm
56-3430	4.5mm x 30mm
56-3435	4.5mm x 35mm
56-3440	4.5mm x 40mm
56-3445	4.5mm x 45mm
56-3450	4.5mm x 50mm
56-3455	4.5mm x 55mm
56-3460*	4.5mm x 60mm
56-3465*	4.5mm x 65mm
56-3470*	4.5mm x 70mm

Standard Multi-Axial Screws (Cont.)

Part #	Description
56-3525	5.5mm x 25mm
56-3530	5.5mm x 30mm
56-3535	5.5mm x 35mm
56-3540	5.5mm x 40mm
56-3545	5.5mm x 45mm
56-3550	5.5mm x 50mm
56-3555	5.5mm x 55mm
56-3560*	5.5mm x 60mm
56-3565*	5.5mm x 65mm
56-3570*	5.5mm x 70mm
56-3575*	5.5mm x 75mm
56-3625	6.5mm x 25mm
56-3630	6.5mm x 30mm
56-3635	6.5mm x 35mm
56-3640	6.5mm x 40mm
56-3645	6.5mm x 45mm
56-3650	6.5mm x 50mm
56-3655	6.5mm x 55mm
56-3660	6.5mm x 60mm
56-3665*	6.5mm x 65mm
56-3670*	6.5mm x 70mm
56-3675*	6.5mm x 75mm
56-3680*	6.5mm x 80mm
56-3725	7.5mm x 25mm
56-3730	7.5mm x 30mm
56-3735	7.5mm x 35mm
56-3740	7.5mm x 40mm
56-3745	7.5mm x 45mm
56-3750	7.5mm x 50mm
56-3755	7.5mm x 55mm
56-3760	7.5mm x 60mm
56-3765*	7.5mm x 65mm
56-3770*	7.5mm x 70mm
56-3775*	7.5mm x 75mm
56-3780*	7.5mm x 80mm
56-3825	8.5mm x 25mm
56-3830	8.5mm x 30mm
56-3835	8.5mm x 35mm
56-3840	8.5mm x 40mm
56-3845	8.5mm x 45mm
56-3850	8.5mm x 50mm
56-3855	8.5mm x 55mm
56-3860	8.5mm x 60mm
56-3865*	8.5mm x 65mm
56-3870*	8.5mm x 70mm
56-3875*	8.5mm x 75mm
56-3880*	8.5mm x 80mm

Self-Tapping Multi-Axial Screws

Part #	Description
58-3425	4.5mm x 25mm
58-3430	4.5mm x 30mm
58-3435	4.5mm x 35mm
58-3440	4.5mm x 40mm
58-3445	4.5mm x 45mm
58-3450	4.5mm x 50mm
58-3455	4.5mm x 55mm
58-3525	5.5mm x 25mm
58-3530	5.5mm x 30mm
58-3535	5.5mm x 35mm
58-3540	5.5mm x 40mm
58-3545	5.5mm x 45mm
58-3550	5.5mm x 50mm
58-3555	5.5mm x 55mm
58-3560*	5.5mm x 60mm
58-3625	6.5mm x 25mm
58-3630	6.5mm x 30mm
58-3635	6.5mm x 35mm
58-3640	6.5mm x 40mm
58-3645	6.5mm x 45mm
58-3650	6.5mm x 50mm
58-3655	6.5mm x 55mm
58-3660	6.5mm x 60mm
58-3665*	6.5mm x 65mm
58-3670*	6.5mm x 70mm
58-3675*	6.5mm x 75mm
58-3680*	6.5mm x 80mm
58-3725	7.5mm x 25mm
58-3730	7.5mm x 30mm
58-3735	7.5mm x 35mm
58-3740	7.5mm x 40mm
58-3745	7.5mm x 45mm
58-3750	7.5mm x 50mm
58-3755	7.5mm x 55mm
58-3760	7.5mm x 60mm
58-3765*	7.5mm x 65mm
58-3770*	7.5mm x 70mm
58-3775*	7.5mm x 75mm
58-3780*	7.5mm x 80mm
58-3825	8.5mm x 25mm
58-3830	8.5mm x 30mm
58-3835	8.5mm x 35mm
58-3840	8.5mm x 40mm
58-3845	8.5mm x 45mm
58-3850	8.5mm x 50mm
58-3855	8.5mm x 55mm

Self-Tapping Multi-Axial Screws (Cont.)

Part #	Description
58-3860	8.5mm x 60mm
58-3865*	8.5mm x 65mm
58-3870*	8.5mm x 70mm
58-3875*	8.5mm x 75mm
58-3880*	8.5mm x 80mm

Set Screw

Part #	Description
56-2001	Set Screw

5.5mm Diameter Lordosed Rods

Part #	Description
54-2040	40mm Rod
54-2050	50mm Rod
54-2060	60mm Rod
54-2070	70mm Rod
54-2080	80mm Rod
54-2090*	90mm Rod
54-2110*	100mm Rod

5.5mm Diameter Straight Rods

Part #	Description
55-2040	40mm Rod
55-2050	50mm Rod
55-2060	60mm Rod
55-2070	70mm Rod
55-2080	80mm Rod
55-2090*	90mm Rod
55-2110*	100mm Rod
55-2111	110mm Rod
55-2112	120mm Rod
55-2114	140mm Rod
55-2116	160mm Rod
55-2118	180mm Rod
55-2120	200mm Rod
55-2145	450mm Rod

* Manufactured to order

Lateral Offset Connectors

Part #	Description
55-6315	SFS Lateral Offset - 15mm
55-6320	SFS Lateral Offset - 20mm
55-6325	SFS Lateral Offset - 25mm

Fixed Cross-Connectors

Part #	Description
57-5315	15mm Fixed Cross-Connector
57-5317	17mm Fixed Cross-Connector
57-5319	19mm Fixed Cross-Connector
57-5321	21mm Fixed Cross-Connector
57-5323	23mm Fixed Cross-Connector
57-5325	25mm Fixed Cross-Connector

Multi-Axial Cross-Connectors

Part #	Description
55-5325	25mm
55-5330	30mm
55-5335	35mm
55-5340	40mm
55-5345	45mm
55-5350	50mm
55-5355	55mm
55-5360	60mm
55-5365	65mm
55-5370	70mm
55-5375	75mm
55-5380	80mm

Hook Implants

Part #	Description
57-2001	Set Screw
57-2145	450mm Rod with Hex Ends
57-2160	600mm Rod with Hex Ends
57-3010	Small Pedicle Hook
57-3011	Large Pedicle Hook
57-3020	Angled Left Hook
57-3021	Angled Right Hook
57-3030	Offset Left Hook
57-3031	Offset Right Hook
57-3040	Narrow Thoracic Laminar Hook
57-3041	Wide Thoracic Laminar Hook
57-3050	Narrow Lumbar Laminar Hook
57-3051	Wide Lumbar Laminar Hook

Domino/Spacers/Washers/Staples

Part #	Description
55-6003	SFS 3mm Spacer
55-6005	SFS 5mm Spacer
55-6102	SFS 2mm Washer
55-6104	SFS 4mm Washer
55-6106	SFS 6mm Washer
55-6202	SFS 2mm Staple
55-6204	SFS 4mm Staple
55-6206	SFS 6mm Staple
55-6420	5.5 to 5.5mm Axial Rod Connector (Spline Drive)
65-6425	3.0 to 5.5mm Axial Rod Connector
55-6805	5.5 x 5.5mm Side By Side Top Loading Rod Connector
65-6405	3.0 x 5.5mm Side by Side Front Loading Rod Connector

Mono-Axial Screws

Part #	Description
55-4425	4.5mm x 25mm
55-4430	4.5mm x 30mm
55-4435	4.5mm x 35mm
55-4440	4.5mm x 40mm
55-4445	4.5mm x 45mm
55-4450	4.5mm x 50mm
55-4455	4.5mm x 55mm
55-4460*	4.5mm x 60mm
55-4465*	4.5mm x 65mm
55-4470*	4.5mm x 70mm
55-4525	5.5mm x 25mm
55-4530	5.5mm x 30mm
55-4535	5.5mm x 35mm
55-4540	5.5mm x 40mm
55-4545	5.5mm x 45mm
55-4550	5.5mm x 50mm
55-4555	5.5mm x 55mm
55-4560*	5.5mm x 60mm
55-4565*	5.5mm x 65mm
55-4570*	5.5mm x 70mm
55-4575*	5.5mm x 75mm
55-4625	6.5mm x 25mm
55-4630	6.5mm x 30mm
55-4635	6.5mm x 35mm
55-4640	6.5mm x 40mm
55-4645	6.5mm x 45mm

Mono-Axial Screws

Part #	Description
55-4650	6.5mm x 50mm
55-4655	6.5mm x 55mm
55-4660	6.5mm x 60mm
55-4665*	6.5mm x 65mm
55-4670*	6.5mm x 70mm
55-4675*	6.5mm x 75mm
55-4680*	6.5mm x 80mm
55-4725	7.5mm x 25mm
55-4730	7.5mm x 30mm
55-4735	7.5mm x 35mm
55-4740	7.5mm x 40mm
55-4745	7.5mm x 45mm
55-4750	7.5mm x 50mm
55-4755	7.5mm x 55mm
55-4760	7.5mm x 60mm
55-4765*	7.5mm x 65mm
55-4770*	7.5mm x 70mm
55-4775*	7.5mm x 75mm
55-4780*	7.5mm x 80mm
55-4825	8.5mm x 25mm
55-4830	8.5mm x 30mm
55-4835	8.5mm x 35mm
55-4840	8.5mm x 40mm
55-4845	8.5mm x 45mm
55-4850	8.5mm x 50mm
55-4855	8.5mm x 55mm
55-4860	8.5mm x 60mm
55-4865*	8.5mm x 65mm
55-4870*	8.5mm x 70mm
55-4875*	8.5mm x 75mm
55-4880*	8.5mm x 80mm

* Manufactured to order

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 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 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: 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.

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 spondylolistheses with objective evidence of neurologic impairment;
b) Fracture;
c) Dislocation;
d) Scoliosis;
e) Kyphosis;
f) Spinal tumor; and
g) Failed previous fusion (pseudoarthrosis).

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).

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) Spondylolistheses;
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).

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. 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. 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 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.
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. DO NOT REUSE IMPLANTS. Discard used, damaged, or otherwise suspect implants.
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. 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.
15. 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.

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

Notes

Distributed by:

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

EC REP
Medical Device Safety Services (MDSS):
Schiffgraben 41
30175, Hannover
Germany
+49 511 6262 8630

CE 0086

RX Only

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. 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.

888.298.5700
www.orthofix.com

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