



Firebird[™]
Spinal Fixation System

OPERATIVE TECHNIQUE



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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.

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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 (IFU) for the complete list of indications, warnings, precautions, and other important medical information.

INTRODUCTION

The Firebird Spinal Fixation System is a comprehensive solution for posterior thoracolumbar surgical cases including degenerative disc disease, minimally invasive as well as deformity procedures. This exceptional system evolved from listening to the demanding requirements and insightful suggestions of industry leading spine surgeons. Orthofix Inc. would like to take this opportunity to thank them for their contributions. Their efforts helped us deliver a versatile selection of devices and ergonomically-designed instrument sets.

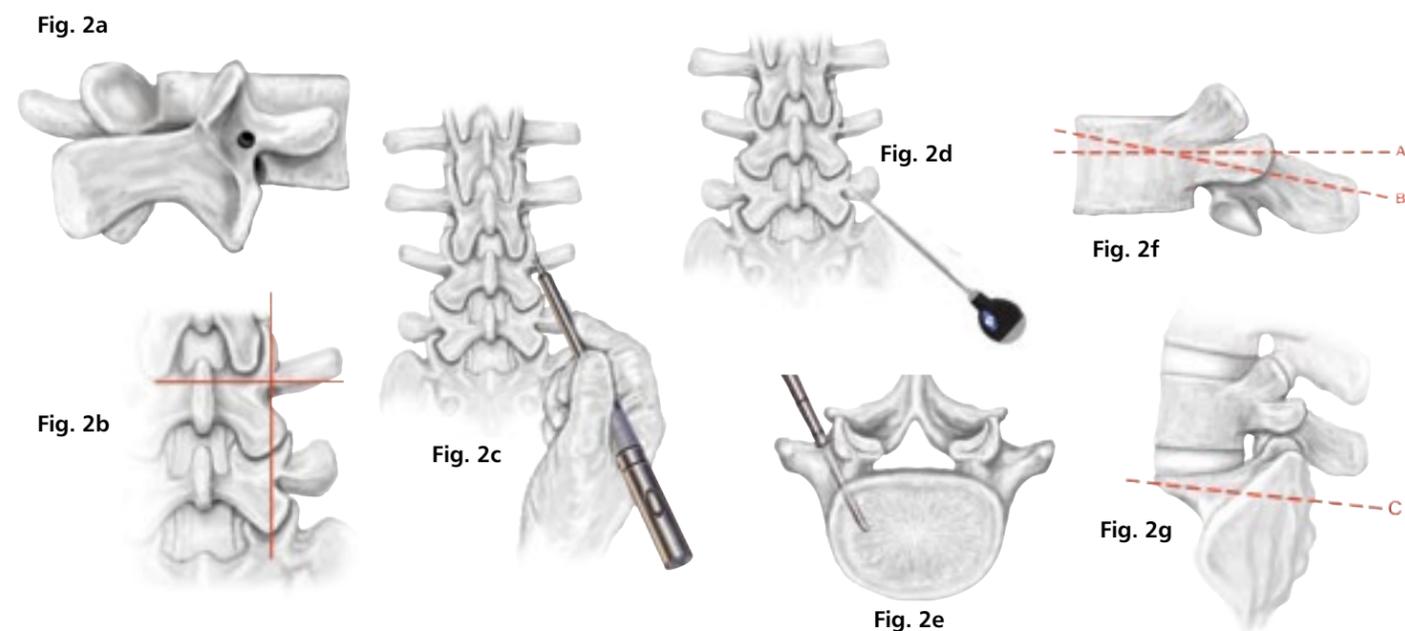




1. PATIENT POSITIONING

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.



2. PEDICLE PREPARATION

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 rongeur 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 allow 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.

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 lower 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).

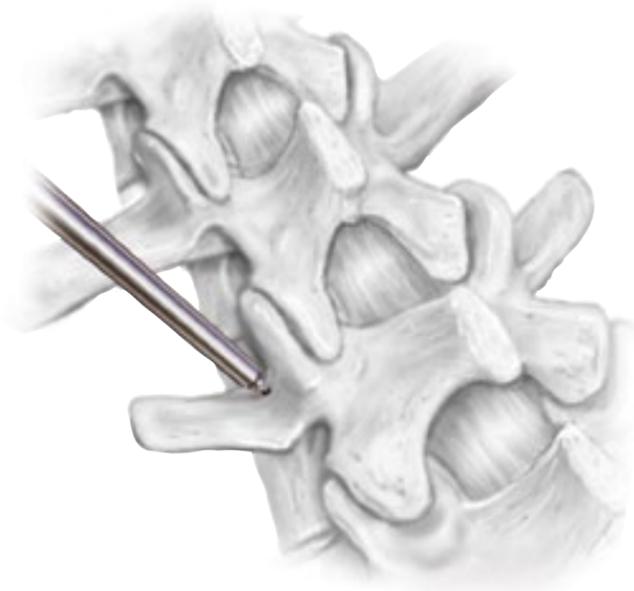


Fig. 3

3. BONE AWL

(52-1001)

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

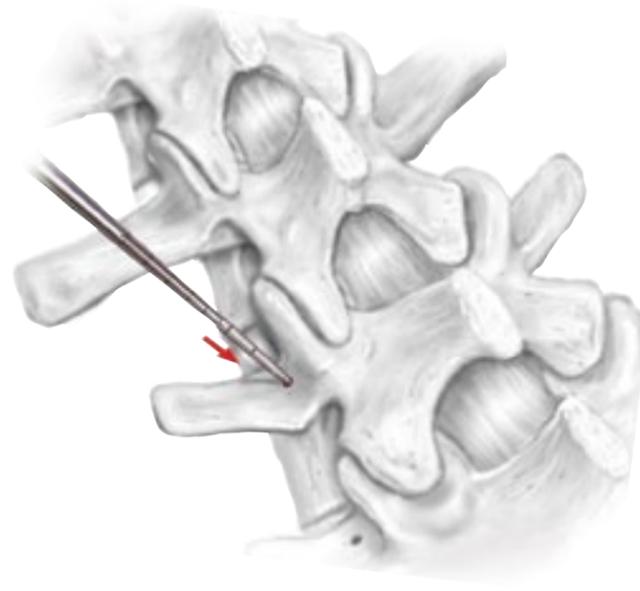


Fig. 4

4. BONE PROBE

(52-1002 Straight / 52-1003 Curved)

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



Fig. 5a

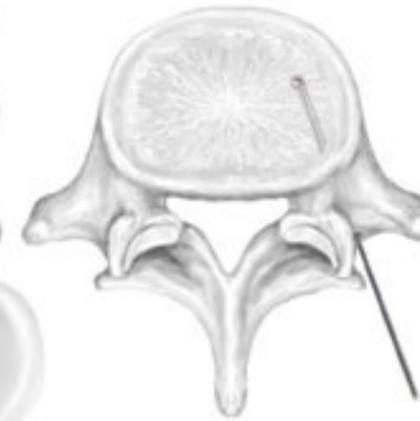


Fig. 5b

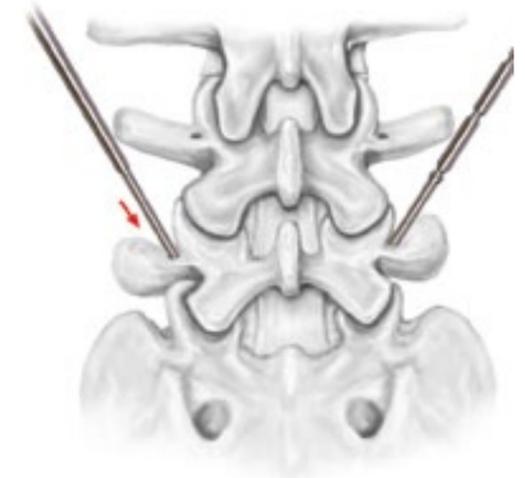


Fig. 6

6. X-RAY MARKERS

(55-1006 Right / 55-1007 Left)

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

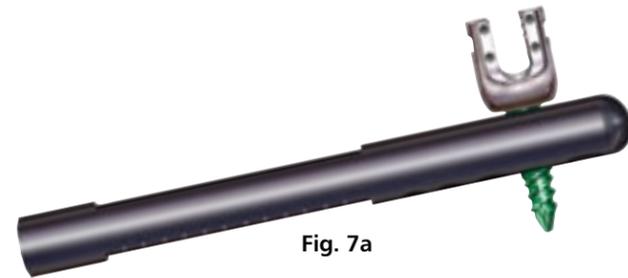


Fig. 7a



Fig. 7b



Fig. 7c

7. SCREW SELECTION

Screw Template (52-1308)

Use the screw template to verify screw diameter (**Fig. 7a**) and length of modular screw (**Fig. 7b**) or multi/mono-axial screw (**Fig. 7c**) prior to insertion.



Fig. 8

8. BONE TAP

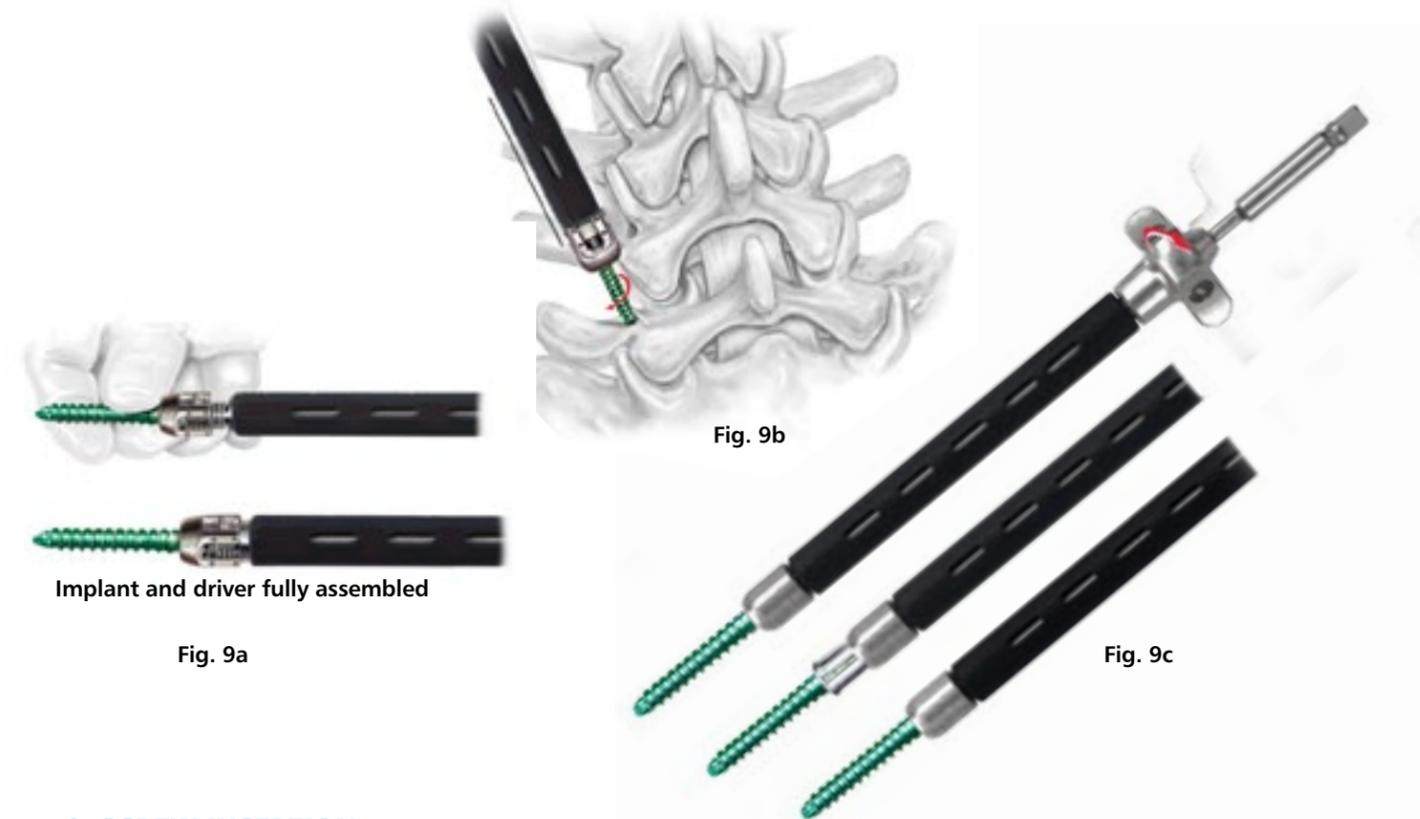
Monolithic (52-1224 thru 52-1228)

Modular (52-1024 thru 52-1028)

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 the tap as a guide.

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

NOTE: To attach your choice of ratcheting handles: straight (52-1013) or T-handle (52-1011) to the modular taps, align the proximal connection of the tap with the center of the ratcheting handle and push firmly into position. To disengage the tap from the handle, retract the shaft connector and firmly tug on the instrument shaft.



Implant and driver fully assembled

Fig. 9a

Fig. 9b

Fig. 9c

9. SCREW INSERTION

Multi-Axial and Mono-Axial Screws

Multi-Axial Screw Driver (52-1831) or

Mono-Axial Screw Driver (52-1830)

Select appropriate screw driver with respect to the pedicle screw being implanted. Insert the distal tip of driver into the body of the pedicle screw. Turn the knob clockwise to thread and secure the pedicle screw to the screw driver tip. (**Fig. 9a**)

NOTE: Ensure the pedicle screw is rigidly fixed on the screw driver tip and is in alignment with the driver shaft prior to screw insertion. Misalignment, improper engagement of screw to driver, or loosening of knob during screw insertion can result in undesired trajectory of pedicle screw. Do not apply levering force to driver during screw insertion as this can result in missed trajectory of screw or pedicle fractures.

Insert the screw into the prepared pedicle until it is positioned to the correct level. The screw should extend approximately 50% to 80% into vertebral body. (**Fig. 9b**) To disengage the screw driver from the screw body, turn the knob counter clockwise until the screw releases from the tip.

NOTE: If multi-axial screws are placed too deeply, full range of motion may be lost. To regain screw body mobility, turn screw body counter clockwise until range of motion is reestablished. For multi-axial and modular screws, the adjustment driver (52-1339) can be used.

Modular Screws

Modular Screw Driver (52-1832)

Attach the appropriate bone screw onto the modular screw driver by placing the head of the bone screw into the collet of the distal tip. Turn the knob clockwise until sleeve completely surrounds the collet (**Fig. 9c**).

NOTE: Ensure the pedicle screw is rigidly fixed on the screw driver tip and is in alignment with the driver shaft prior to screw insertion. Misalignment, improper engagement of screw to driver, or loosening of knob during screw insertion can result in undesired trajectory of pedicle screw. Do not apply levering force to driver during screw insertion as this can result in missed trajectory of screw or pedicle fractures.



Fig. 10a

Fig. 10b

10. DECORTICATION

Decorticating Planer (52-1334)

Place the decorticating planer over the spherical head of the bone screw (**Fig. 10a**). Rotate the planar surface clockwise and counterclockwise to decorticate bone (**Fig. 10b**) and allow for proper seating of modular body providing full range of motion.

NOTE: For modular bone screws only.



11. MODULAR BODY ATTACHMENT

Attach the appropriate modular body to the holder (51-7100) (**Fig. 11a**), by aligning the pin holes on body with inserter and clamp. Slide the body onto the bone screw by applying an axial force to connect the base of the body to the spherical head of the bone screw (**Fig. 11b and 11c**). The pressure cap will move freely in the body to allow for proper insertion.

Confirm a secure connection between the body and bone screw by pulling up on the holder prior to disconnecting. When the body remains attached to the bone screw the assembly is secure. (**Fig. 11d**)

NOTE: For modular bone screws only.



Fig. 11a

Fig. 11b

Fig. 11c

Fig. 11d

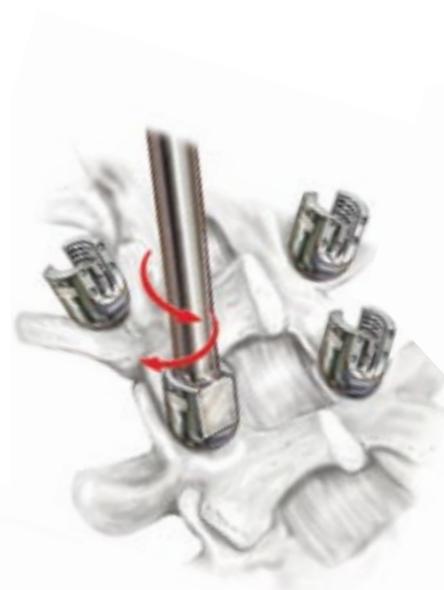


Fig. 12a

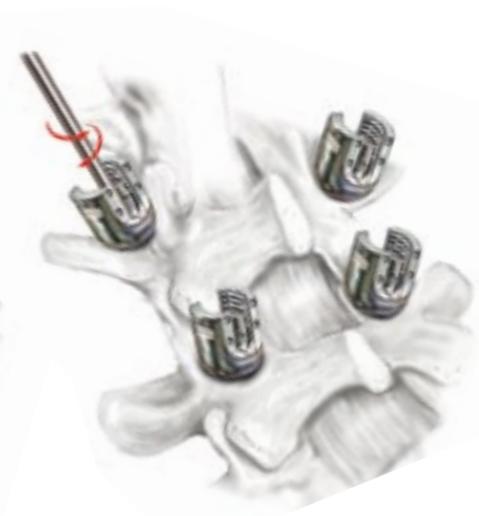


Fig. 12b



Fig. 13



Fig. 14

DESCRIPTION OF SCREW BODY OPTIONS

Top-Loading (44-2101)

Insert the rod from a top orientation prior to preliminarily securing with set screw.

Closed (44-2102)

Insert the body onto the rod at the end of the spinal construct prior to preliminarily securing with set screw.

Reduction (44-2103)

Insert the rod from a top orientation prior to preliminarily securing with set screw. Break off tabs after set screw is below the line of the extended tabs.

Low Profile Offset (51-6408, 51-6411, 51-6414)

Secure the low profile offset to the bone screw. Insert the rod into the offset tulip prior to preliminarily securing with set screw.

12. SCREW ADJUSTMENT

Head Adjuster (52-1038)

Use the head adjuster to align the top opening bodies of the multi-axial screw prior to rod insertion (Fig 12a).

Multi-Axial Adjustment Driver (52-1339)

Use the multi-axial adjustment driver to adjust the sagittal height of the pedicle screws prior to rod insertion (Fig 12b).

NOTE: This instrument can assist in restoring mobility of the multi-axial bodies if screw has been buried too deep.

13. ROD PREPARATION

Rod Template

Determine the rod contour and length required using the trial rod (52-1040 thru 52-1042).

Rod Selection

NOTE: Based on surgeon evaluation of rod stiffness requirements and patient need, Cobalt Chrome rods may be used as an alternative to Titanium rods.

NOTE: Both rod materials are compatible with standard Titanium Firebird implants.

14. ROD CUTTING

Rod 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.

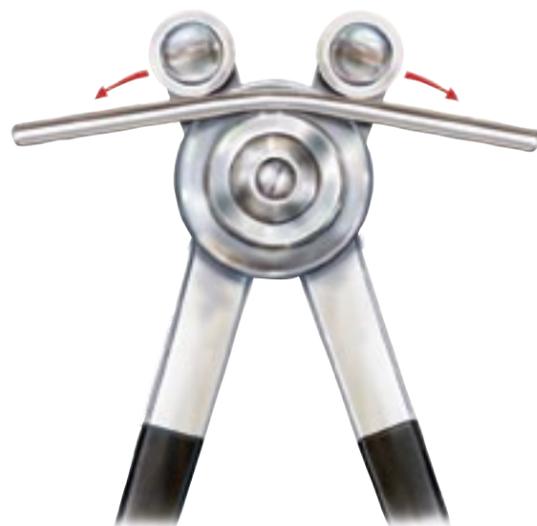


Fig. 15

15. ROD CONTOURING

Rod Bender (52-1046)

Utilizing the rod bender, create the correct contour, referencing the rod template as a guide.



Fig. 16

16. ROD INSERTION

Rod Inserter (52-1581)

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

NOTE: Avoid applying unnecessary lateral bending or rotational force to rod inserte

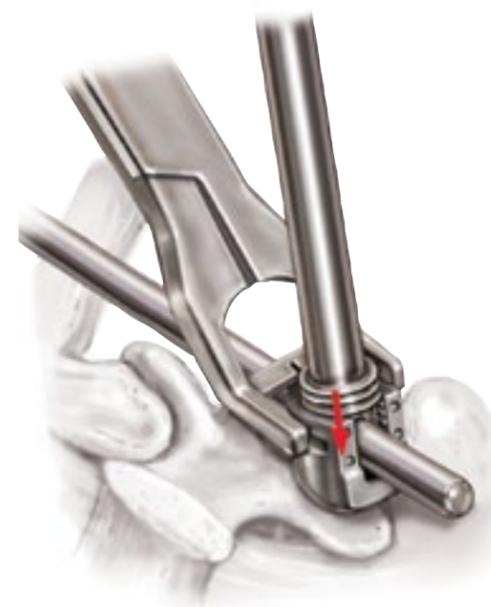


Fig. 17a

17. ROD REDUCTION

Rocker (52-1251)

Attach rocker to pedicle screw body and lever rod until seated in the pedicle screw (**Fig. 17a**)
Proceed to Step 17b

Rod Pusher (52-1050)

Position rod pusher tip on rod and apply axial force until rod is seated in pedicle screw body (**Fig. 17b**)
Proceed to Step 18



Fig. 17b



Fig. 17c

Rod Reducer (52-1755)

Slide rod reducer tip over from the pedicle screw body and seat pins into indents. Take care to align inner shaft with rod prior to reduction (**Fig. 17c**).

NOTE: Unnecessary lateral bending or rotational force may cause reducer to slip from screw head during reduction or the inability to properly insert set screw.

NOTE: Applying too much reduction force to screws can result in screw pullout.

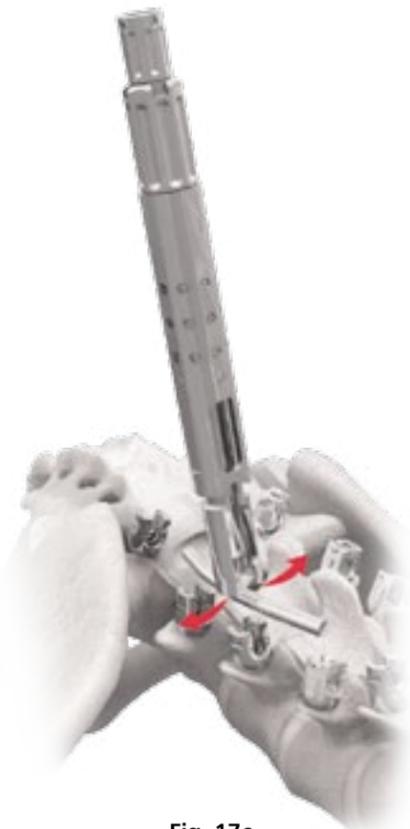


Fig. 17c

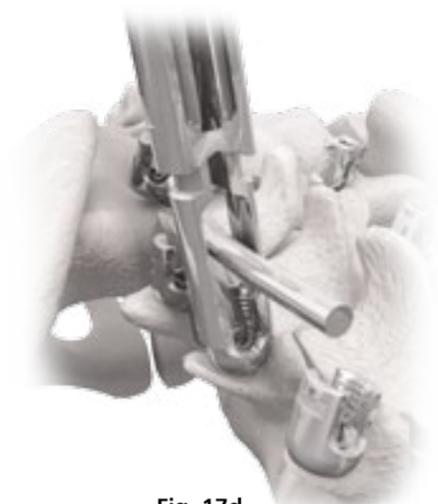


Fig. 17d



Fig. 17e



Fig. 17f



Fig. 17g



Fig. 17h

Rod Reduction with Rod Reducer (51-1989)

To expand the distal tip of the Tubular Rod Reducer into its fully unlocked position, turn the drive knob on the proximal end counter-clockwise until flush with the reduction tube. To set the distal tip into the stab-and-grab function, thread the reduction tube proximally only until it meets noticeable resistance. It will naturally slide into this position approximately 3mm from drive knob.

Capture the rod in the slot at the distal tip. Match the pins on the inside of the distal end of the inner tube with the two pin holes on the outside of the modular screw body. In the fully open position, the inside of the slotted tip will bottom out on the top flats of the screw body. With the stab-and-grab function, the tip will click into place, capturing the modular screw body. (Fig 17c & 17d)

CAUTION: When using the reducer in the fully open position, the instrument can become jammed if it is angled on the modular screw body. If it becomes jammed during reduction, shift the reducer until it clicks into place.

Rod reduction is achieved by gently holding the outer reduction sleeve and turning the drive knob clockwise. The instrument will provide up to 28mm of reduction travel. (Fig 17e & 17f)

If resistance is encountered, the optional driver, Tubular Rod Reducer (51-1990) may be attached to the desired Ratcheting Handle. Slide the Driver over the retention sleeve at the very proximal end, being careful to match the ends of the Driver with the notches in the drive knob. Turn Driver clockwise to complete the reduction maneuver. Complete reduction has been achieved when the drive knob cannot be turned any further. (Fig 17g)

Remove the Driver and insert a set screw with provisional tightening using Set Screw Holder/Driver, Short (52-1059).

To remove the Tubular Reducer (Fig 17h) after complete reduction, simply turn the drive knob counter-clockwise past the stab-and-grab position and the Tubular Reducer will lift off the modular screw body.



Fig. 18



Fig. 19a



Fig. 19b

18. ROD FIXATION

Set Screw Holder/Driver, Short (52-1059)

Turn the driver clockwise to thread set screw into the pedicle screw body and preliminarily fixate the rod.

19. ROD MANIPULATIONS

Option A:

In-situ Rod Benders (52-1070, 52-1071)

Position the in-situ rod benders on rod. Gently pull rod benders apart to create a bend in the rod in the sagittal plane and increase rod lordosis.

NOTE: For more complex coronal plane deformities, the use of coronal benders (51-1475, 51-1476) will be needed.

Option B:

Rod Gripper (51-1480)

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

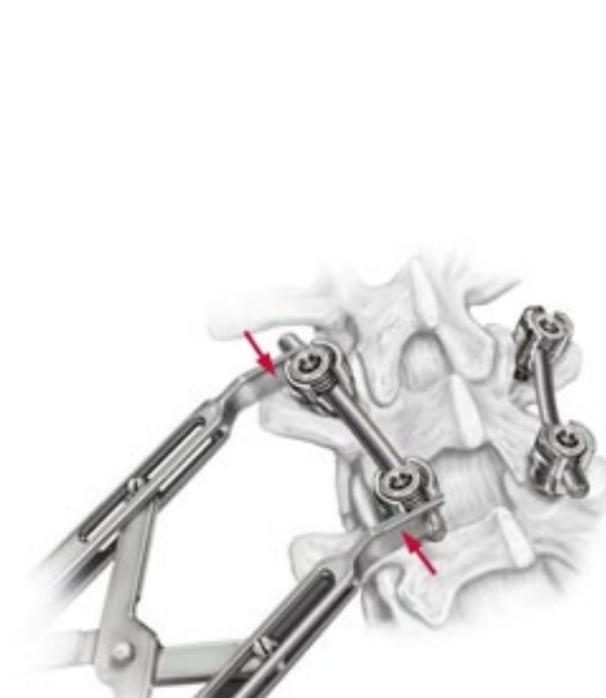


Fig. 20

20. COMPRESSION/DISTRACTION

Distractor (52-1590)

Compressor (52-1591)

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 holder/driver. Compress against the appropriate modular body while tips remain on rod 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.

Distraction across modular screws, before modular body attachment, can be performed by utilizing the hinged distractor (52-1890) in between screws and cup screw heads within tips. To distract, place arms of distractor under modular screw head and turn knob clock-wise for distraction.

NOTE: Applying too much compression or distraction force to screws can result in pedicle fracture.



Fig. 21

21. FINAL TIGHTENING

Counter Torque Wrench (52-1765)

Set Screw Driver (52-1061)

Torque Limiting Handle (52-1512)

Position the counter torque wrench over the pedicle screw and rod making sure to engage tips to align rod within screw body. Place the set screw driver through the cannulation of the counter torque wrench and into the hex of the set screw. Turn the torque limiting handle clockwise and apply counter torque with the counter torque wrench to tighten the set screw to 100 in-lbs. The torque limiting handle will reach its maximum torque and release at 100 in-lbs.

NOTE: Insert the set screw driver into the torque limiting handle by compressing connection mechanism. Ratcheting feature will not function properly unless driver is fully seated before releasing connection mechanism. Ensure the ratcheting dial is set to forward "F" prior to engaging the set screw.



Fig. 20b

CROSS-CONNECTORS

Cross-Connector Calipers (52-1101)

Cross-Connector Benders, Right (52-1102) and
Left (52-1103)

Cross-Connector Driver (52-1104)

The appropriate size cross-connector is determined with the cross-connector calipers. 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, right and left. 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.

IMPLANT REMOVAL

Set Screw Driver (52-1061)

Counter Torque Wrench (52-1765)

Multi-Axial Adjustment Driver (52-1339)

Mono-Axial Screw Driver (52-1830)

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 screw. Use of counter torque wrench is recommended to avoid damage to the pedicle. (**Fig. 20b**) Carefully remove all set screws. The multi-axial adjustment driver can be utilized to remove the screw assemblies. The multi-axial adjustment driver must be used to remove bone screws that are attached to offset heads.

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

REDUCTION HEAD TECHNIQUE



Fig. 1

1. MODULAR BODY ATTACHMENT

Place modular bone screw as described in steps 8-10 of this operative technique.

Attach the Reduction Body (44-2103) to the modular screw in the same manner as described in step 11 of this operative technique.



Fig. 2

2. ROD PLACEMENT

After placing the rod into the saddles, insert setscrews into the screws cephalad and caudal to the reduction target. Tighten all setscrews caudal to the reduction screw with the torque wrench and counter torque wrench and leave the setscrews cephalad of the reduction loose. The opposite approach is equally functional. This step will allow for relative lengthening of the spine during reduction procedure (**Fig. 2b**).

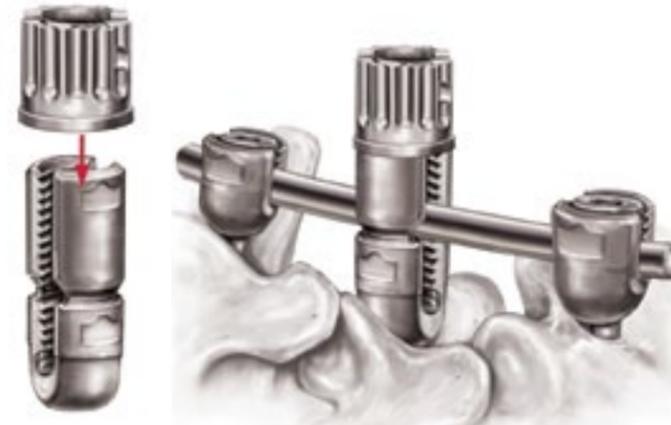


Fig. 3

3. ANTI-SPLAY CAP ATTACHMENT

Slide an Anti-Splay Tool (68-0111) down each reduction screw body head until it rests against the rod and rotate clockwise to lock anti-splay cap to the reduction head. (**Fig. 3**).



Fig. 4

4. SET SCREW PLACEMENT

Introduce a setscrew into each reduction screw body. Advance the setscrews in unison or back-and-forth from one setscrew to the other. The anti-splay rings will ride down the setscrew body with the rod as the setscrew is advanced (**Fig. 4**).

Note: Do not remove the anti-splay tools until all tabs are removed, end of step 5.



Fig. 5a

5a. ANTI-SPLAY CAP REMOVAL

Once the set screw is passed the tab break points, the anti-splay cap can be removed using the anti-splay cap remover (61-0112)(Fig 5a).

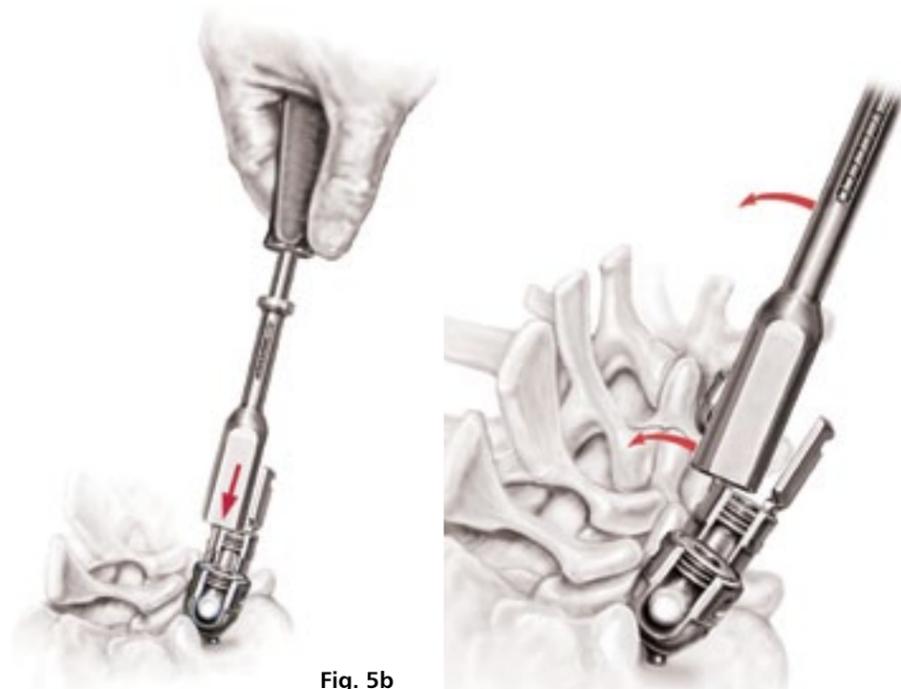


Fig. 5b

5b. TAB REMOVAL

Once the anti-splay cap has been removed, the tabs can then be broken using the tab removal tool (61-0400) (Fig 5b).



Fig. 5c

5c. TAB REMOVAL

After removal of each tab, compress the distal end of the Tab Removal Tool and its handle to eject the removed tab (Fig 5c).

Repeat step 5 for the remaining tabs.

Replace with final tightening from balance of technique.

CASE 1

Instruments

	Part #	Description	Qty Set
	52-1001	Bone Awl	1
	52-1002	Bone Probe, Straight, Large	1
	52-1003	Bone Probe, Curved, Large	1
	52-100X	Dual Sounder, Small	1
		Dual Sounder, Large	1
	52-1011	Ratcheting Handle, T-Handle	1
	52-1013	Ratcheting Handle, Straight, Small	1

CASE 1 (cont)

Instruments

	Part #	Description	Qty Set
	55-1006	X-ray Marker, Right	6
	55-1007	X-ray Marker, Left	6
	52-1024	4.5mm Bone Tap, Modular	1
	52-1025	5.5mm Bone Tap, Modular	1
	52-1026	6.5mm Bone Tap, Modular	1
	52-1027	7.5mm Bone Tap, Modular	1
	52-1028	8.5mm Bone Tap, Modular	1
	N/A	Rubber Mat	1

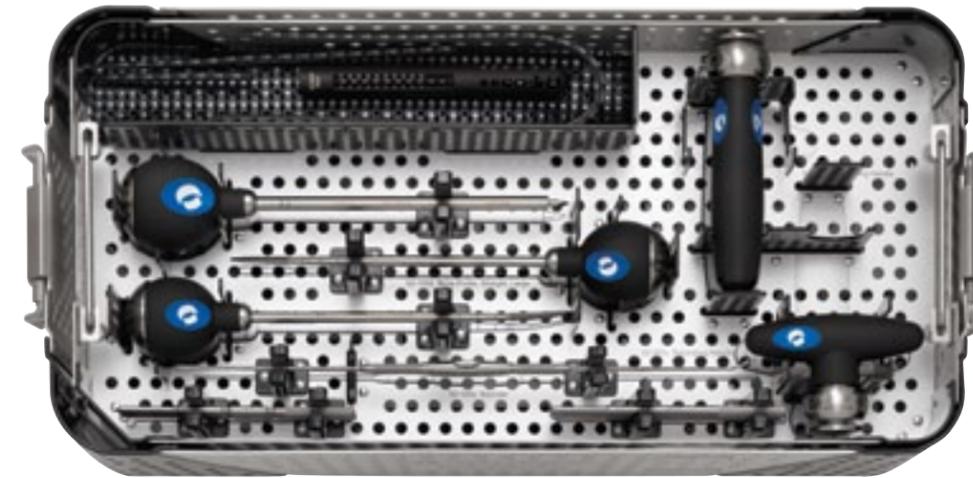
CASE 1 (cont)

Instruments

Part #	Description	Qty Set
52-1830	Mono-Axial Screw Driver	2
52-1831	Multi-Axial Screw Driver	2
52-1832	Modular Screw Driver	2
XX-XXXX		
XX-XXXX		

CASE 1 (cont)

Trays



Tray 1
Level 1



Tray 1
Level 2

CASE 2

Instruments

Part #	Description	Qty Set
51-7100	Head Inserter	2
		
52-1011	Ratcheting Handle	1
		
52-1038	Head Adjuster	1
		
52-1334	Decorticating Planer	1
		
52-1339	Multi-Axial Adjustment Driver1	1
		
52-1581	Rod Inserter	1
		

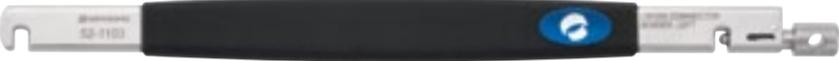
CASE 2 (cont)

Instruments

Part #	Description	Qty Set
52-189x	Hinged Distractor	1
		
52-1059	Set Screw Holder / Driver, Short	2
		
52-1061	Set Screw Driver	2
		
52-1101	Cross-Connector Caliper	1
		

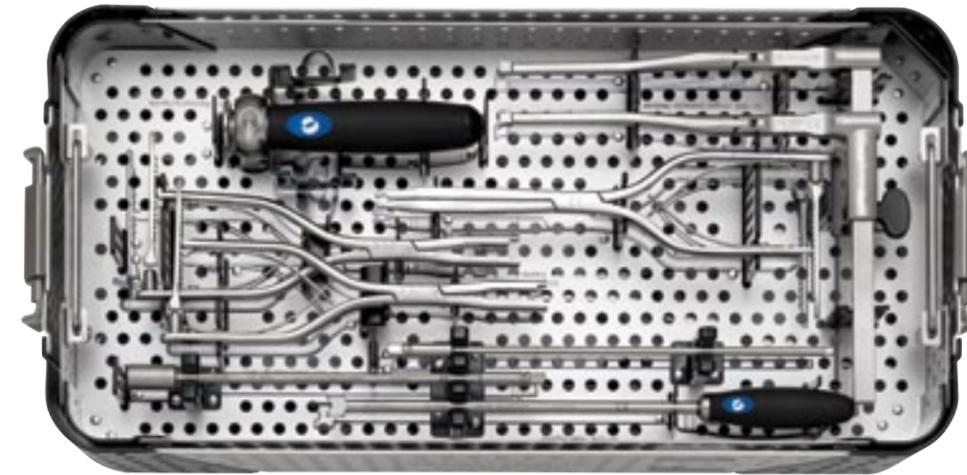
CASE 2

Instruments

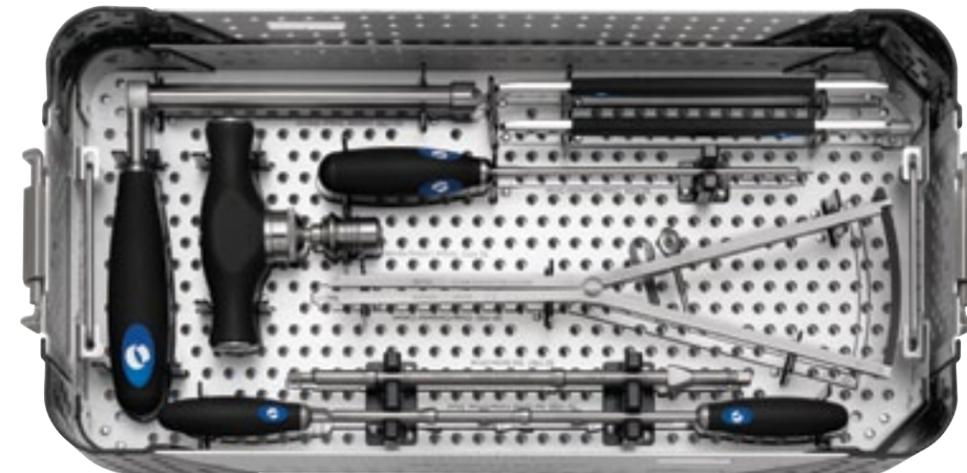
	Part #	Description	Qty Set
	52-1102	Cross-Connector Bender, Right	1
	52-1103	Cross-Connector Bender, Left	1
	52-1104	Cross-Connector Driver	1
	52-1512	Torque Limiting Handle	1
	52-1765	Counter Torque Wrench	1

CASE 2 (cont)

Trays



Tray 2
Level 1



Tray 2
Level 2

CASE 3

Instruments

	Part #	Description	Qty Set
	51-1989	Tubular Rod Reducer	2
	51-1990	Driver, Tubular Rod Reducer	1
	52-1011	Ratcheting Handle	1
	52-1046	Rod Bender	1
	52-1050	Rod Pusher	1
	52-1251	Rod Rocker	1

CASE 3 (cont)

Trays

	Part #	Description	Qty Set
	52-1755	Rod Reducer	1
	51-1480	Rod Gripper	1
	52-107x	In-Situ Rod Bender	1

CASE 3 (cont)

Instruments

Part #	Description	Qty Set
52-1590	Distractor	1

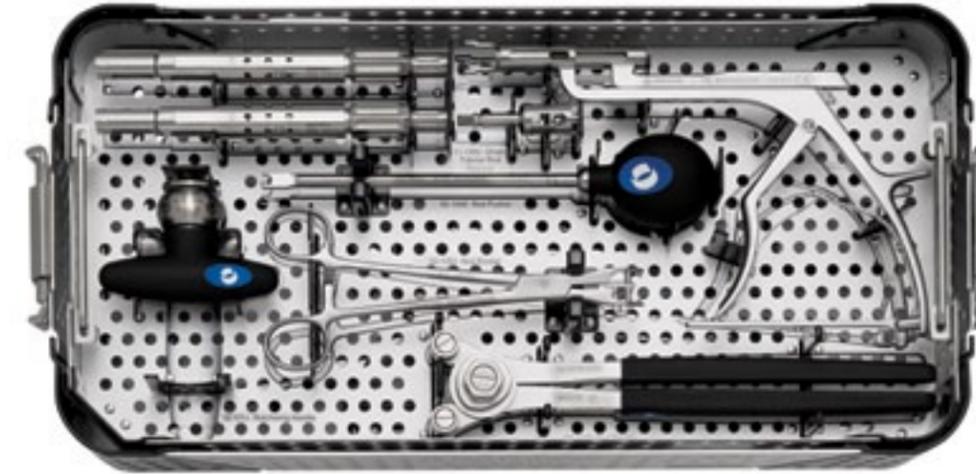


52-1591	Compressor	1
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CASE 3 (cont)

Trays



Tray 3
Level 1



Tray 3
Level 2

Description: The Firebird Spinal Fixation System is a temporary, multiple component system comprised of a variety of non-sterile, single use components, made of titanium alloy or cobalt chrome alloy, that allow the surgeon to build a spinal implant construct. The system is attached to the vertebral body by means of screw fixation to the non-cervical spine. The Firebird Spinal Fixation System consists of an assortment of pedicle screws, set screws, lateral offsets, bone screws and screw bodies. The Firebird Spinal Fixation System implants are not compatible with components or metal from any other manufacturer's system.

Indications: The Firebird Spinal Fixation System is intended for posterior, non-cervical pedicle fixation. The system is limited to skeletally mature patients and is intended to be used as an adjunct to fusion using autograft or allograft. The device is indicated for all of the following indications:

1. degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies)
2. spondylolisthesis,
3. trauma (i.e., fracture or dislocation),
4. spinal stenosis,
5. deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis),
6. tumor,
7. pseudoarthrosis, and
8. failed previous fusion

The Firebird Spinal Fixation System components are used with certain components of the SFS system, including rods, rod connectors and cross connectors.

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 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
17. 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 severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, 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. Non-sterile; the screws, rods, dominos, lateral offsets, spacers, staples, washers, locking nuts, cross connectors, and instruments are sold non-sterile, and therefore must be sterilized before use.
6. To facilitate fusion, a sufficient quantity of autologous bone or other appropriate material should be used.
7. Failure to achieve arthrodesis will result in eventual loosening and failure of the device construct.

8. Excessive torque applied to the screws may strip the threads in the bone.
9. DO NOT REUSE IMPLANTS. Discard used, damaged, or otherwise suspect implants.
10. 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.
11. 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.
12. Mixing of dissimilar metals can accelerate the corrosion process. Do not use the titanium alloy or cobalt chrome alloy components of this system with implants of other material composition or components from different manufacturers unless specifically stated.
13. Reuse of devices labeled as single-use could result in injury or re-operation due to breakage or infection. Do not attempt to re-sterilize single-use implants that come in contact with body fluids.
14. The Firebird Spinal Fixation System has not been evaluated for safety and compatibility in the MR environment, nor has the Firebird Spinal Fixation System been tested for heating or migration in the MR environment.

Cleaning:

All instruments and implants must first be cleaned using established hospital methods before sterilization and introduction into a sterile field. Additionally, all instruments and implants that have been previously taken into a sterile surgical field must first be cleaned using established hospital methods before sterilization and reintroduction into a sterile surgical field. Cleaning can include the use of neutral cleaners followed by a deionized water rinse. All products should be treated with care. Improper use or handling may lead to damage and possible improper functioning of the device.

Sterilization:

The Firebird Spinal Fixation System should be sterilized by the hospital using one of the following recommended cycles when utilizing an FDA cleared sterilization wrap:

Method: Steam (wrapped)	Or:	Method: Steam (wrapped)
Cycle: Gravity		Cycle: Prevac
Temperature: 270°F (132°C)		Temperature: 270°F (132°C)
Exposure time: 15 minutes		Exposure time: 4 minutes
Drying time: 30 minutes		Drying time: 30 minutes

Physician Information

Pre-operative:

1. Only patients that meet the criteria described in the indications should be selected.
2. Patient conditions and/or predispositions such as those addressed in the aforementioned contraindications should be avoided.
3. Correct selection of the implant is extremely important.
4. Use care in handling and storage of implant components. Cutting, bending, or scratching the surface of metal components can significantly reduce the strength and fatigue resistance of the implant system and should be avoided. These, in turn, may cause cracks and/or internal stresses that are not obvious to the eye and may lead to fracture of the components. Inspection should be made to determine if components have been damaged during storage or previous procedures.
5. An adequate inventory of implant sizes should be available at the time of surgery.
6. Certain special surgical instruments are required to perform this surgery. Review of the use and handling of these instruments is very important.

Intra-operative:

1. The two primary goals of surgery with the Firebird Spinal Fixation System are to correct the deformity presented and to arthrodesis selected vertebrae. Adequate exposure bony preparation and grafting is essential to achieving these results.
2. Whenever possible, use pre-cut rods of the length needed. The rods should not be repeatedly or excessively bent any more than absolutely necessary. The rods should not be reverse bent in the same location. Use great care to insure that the implant surfaces are not scratched or notched in any way. If the rods are cut to length, they should be cut in such a way as to create a flat, non-sharp surface perpendicular to the midline of the rod. Cut the rods outside the operative field.
3. The use of two rods and cross connecting the rods will provide a more rigid construct.
4. The placement of screws should be checked radiographically prior to assembly of the rod construct.
5. Care should be taken when positioning the implants to avoid neurological damage.
6. To facilitate proper fusion below and around the location of the instrumentation, a bone graft should be used.
7. Confirm that the rods are fully seated in the bottom of the screw head. Rods that are not fully seated may prevent the device from locking together.
8. Before closing the soft tissues, all of the set screws should be tightened firmly with a torque wrench or screwdriver according to the operative technique. Recheck the tightness of all screws and nuts to make sure that none loosened during the tightening of the other set screws. Failure to do so may cause loosening of the other components.
9. Bone cement should not be used since this material will make removal of the component difficult or impossible. The heat generated from the curing process may also cause neurological damage and bone necrosis.

Postoperative:

1. Detailed instructions on the use and limitations of the implant should be given to the patient. The patient must be made aware of the limitations of the implant. Physical activity and load bearing have been implicated in premature loosening, bending, or fracture of internal fixation device.

2. Periodic X-rays for at least the first year postoperatively are recommended for close comparison with postoperative conditions to detect any evidence of changes in position, nonunion, loosening, and bending or cracking of components.
3. Surgical implants must never be reused. Any retrieved devices should never be reused in another surgical procedure. The retrieved parts should be handled and disposed of in such a manner as to ensure that reuse is not possible.
4. To allow the maximum potential for a successful surgical result, the patient or device should not be exposed to mechanical vibration that may loosen the device construct.
5. These implants are temporary internal fixation devices. Internal fixation devices are designed to assist in the stabilization of the operative site during normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. In most cases removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. If the device is not removed following completion of its intended use, complication may occur as follows:
 - a) Corrosion, with localized tissue reaction or pain.
 - b) Migration of implant position resulting in injury.
 - c) Risk of injury from postoperative trauma.
 - d) Bending, loosening and/or breakage, which could make removal impractical or difficult.
 - e) Pain, discomfort or abnormal sensations due to the presence of the device.
 - f) Possible increased risk of infection.
 - g) Bone loss caused by stress shielding.

Adequate postoperative management to avoid fracture, re-fracture or other complications should follow implant removal.

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 the company, Orthofix Inc.

