SeaSpine.

6

F



CONTENTS

FIREBIRD[®]

INTRODUCTION	4
PRE-OPERATIVE	4–5
OPERATIVE TECHNIQUE	6–27
REDUCTION HEAD TECHNIQUE	28–34
INSTRUMENT CATALOG	35–47

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

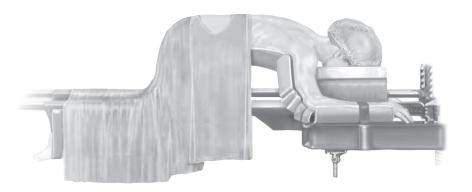
INTRODUCTION

The Firebird[®] Spinal Fixation System is a comprehensive solution for posterior thoracolumbar surgical cases including degenerative disc disease and deformity procedures. This exceptional system has evolved from valuable feedback from the surgeon community. Orthofix[®] would like to take this opportunity to thank them for their contributions. The efforts of all involved has made the Firebird Spinal Fixation System one of the most versatile platforms for spinal fusion.

STEP 1. PATIENT POSITIONING

The patient is placed on the operating room table in a prone position (FIG. 01).

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.



STEP 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. 02A). 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. 02B). 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. 02C).

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.

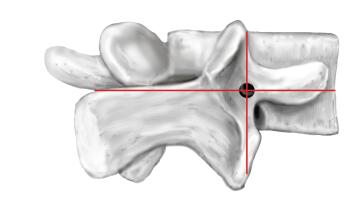


FIG. 02A

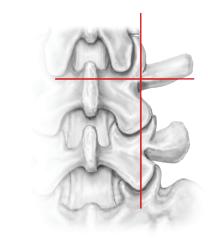


FIG. 02B



FIG. 02C

STEP 2. PEDICLE PREPARATION CONTINUED

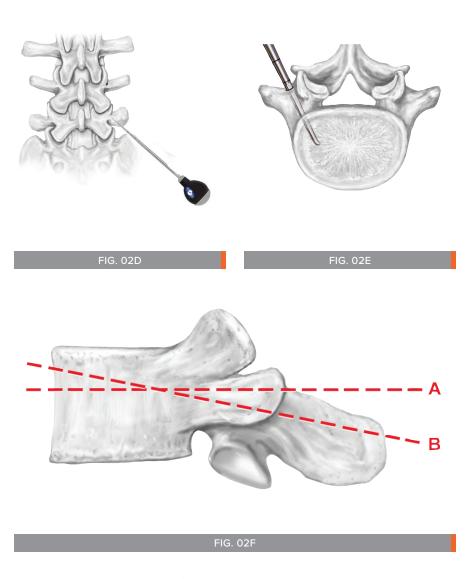
Preparation of the Pedicle Canal

Note that the sagittal plane inclination of the probe should be parallel to the adjacent vertebral endplate (FIG. 02D). 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. 02E). This maneuver will place the pedicle screw entry hole below and away from the unfused superior facet joint (FIG. 02F).

The S1 sacral entry point should be placed at the caudal portion of the S1 pedicle. The probe is then angled 25 to 30° 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. 02G).

NOTE

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



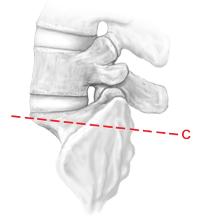
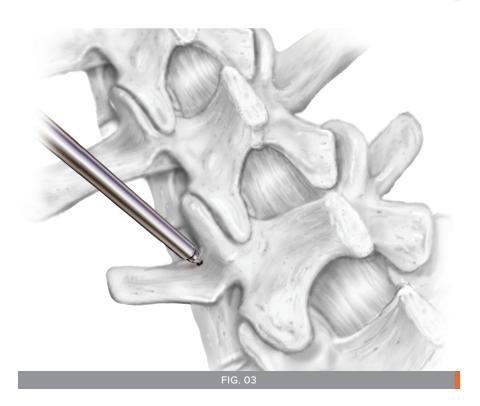


FIG. 02G

STEP 3. BONE AWL

(52-1001)

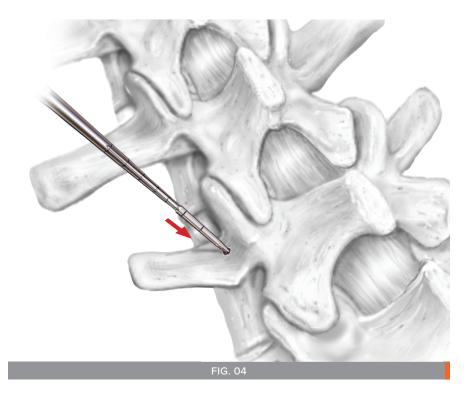
Penetrate the cortex of the bone with the bone awl to create a pilot hole at the pedicle entry point (FIG. 03).



STEP 4. BONE PROBE

Straight Bone Probe (52-1002) Curved Bone Probe (52-1003)

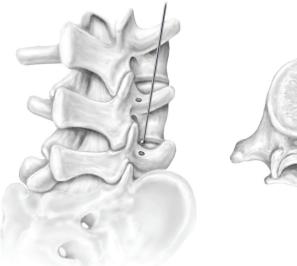
Use the straight or curved bone probe to the desired depth in the pedicle canal, staying within the pedicle walls (FIG. 04).



STEP 5. SOUNDER

Small Sounder (52-1004) Large Sounder (52-1005)

Use the sounder to evaluate the integrity of the cortical wall of the pedicle (FIG. 05A). Choose the appropriate tip and internally palpate the wall or canal of the pedicle to ensure the wall is not perforated (FIG. 05B).



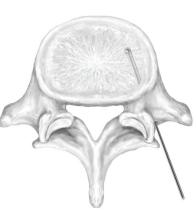


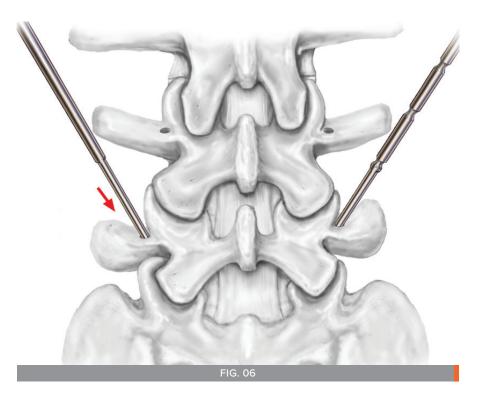
FIG. 05A

FIG. 05B

STEP 6. X-RAY MARKERS

Right X-ray Marker (55-1006) Left X-ray Marker (55-1007)

Use the right and left X-ray markers to confirm pedicle trajectory under fluoroscopy prior to pedicle screw insertion (FIG. 06).



STEP 7. SCREW SELECTION

Screw Template (52-1308)

Use the screw template to verify screw diameter (FIG. 07A) and length of modular screw (FIG. 07B) or multi/mono-axial screw (FIG. 07C) prior to insertion.



=IG. 07A



STEP 8. BONE TAP

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 (FIG. 08).

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.



IG. 08

STEP 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. 09A).

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 may result in missed trajectory of screw or pedicle fractures.

Insert the screw into the prepared pedicle until is it positioned to the correct level. The screw should extend approximately 50% to 80% into the vertebral body (FIG. 09B). To disengage the screw driver from the screw body, turn the knob counterclockwise 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.





FIG. 09A IMPLANT AND DRIVER FULLY ASSEMBLED



FIG. 09B

STEP 9. SCREW INSERTION CONTINUED

Modular Screws Modular Screw Driver (36-1838)

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. 09C).

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 may 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.

NOTE

Optional sterile packed HA coated bone screws are available upon request.



=IG. 09C

STEP 10. DECORTICATION

Decorticating Planar (52-1334)

After placement of modular bone screw, place the decorticating planar 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.



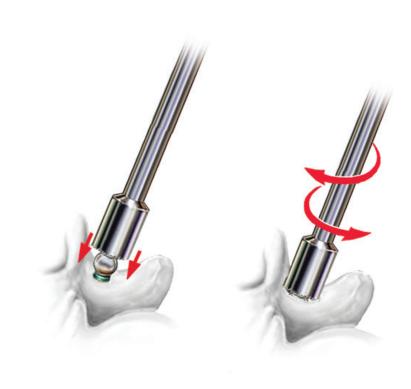




FIG. 10B

DESCRIPTION OF SCREW BODY OPTIONS

Top-Loading (44-2101)

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

Closed (44-2102)

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

Reduction (44-2103)

Insert the rod from a top orientation prior to securing with set screw. Break off tabs after set screw is below the line of the extended tabs. See Reduction Implant procedure page 28.

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 securing with set screw.





TOP-LOADING

REDUCTION





STEP 11. MODULAR BODY ATTACHMENT

After placement of the modular bone screw, 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–11C). The pressure cap will move freely in the body to allow for proper insertion.

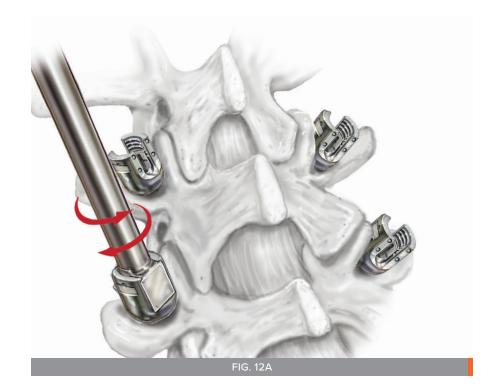
Confirm a secure connection between the body and bone screw by pulling up on the holder prior to disconnecting. When the body remains attached to the bone screw the assembly is secure (FIG. 11D).



STEP 12. SCREW ADJUSTMENT

Head Adjuster (52-1038)

Use the head adjuster to align the top opening bodies of the multiaxial screw prior to rod insertion (FIG. 12A).

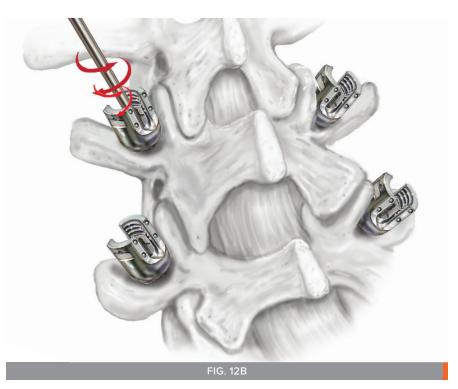


Multi-Axial Adjustment Driver (52-1339)

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.



STEP 13. ROD PREPARATION

Rod Template

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

Rod Selection

NOTE

When there is need for a stiffer rod, Cobalt Chrome rods may be used as an alternative to Titanium rods.

NOTE

Both rod materials are compatible with standard Titanium Firebird implants.



STEP 14. ROD CUTTING

Pin Cutter (55-1041)

Order by Request

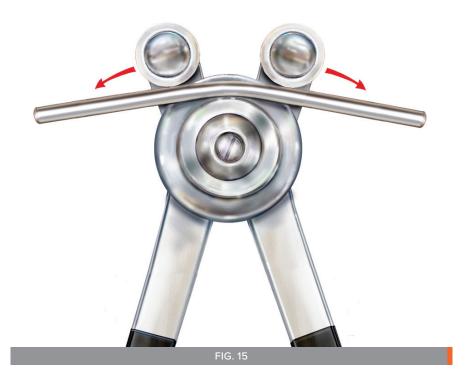
Once the correct length is established, use the rod cutter to cut rod to the desired length referencing the rod template as a guide.



STEP 15. ROD CONTOURING

Rod Bender (52-1046)

Utilizing the rod bender, create the correct contour (FIG. 15), referencing the rod template as a guide. See Step 13 for determining rod length.



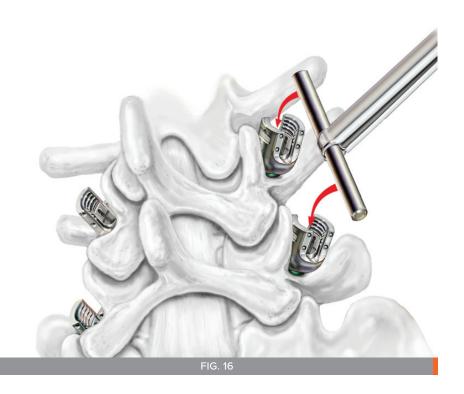
STEP 16. ROD INSERTION

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 (FIG. 16).

NOTE

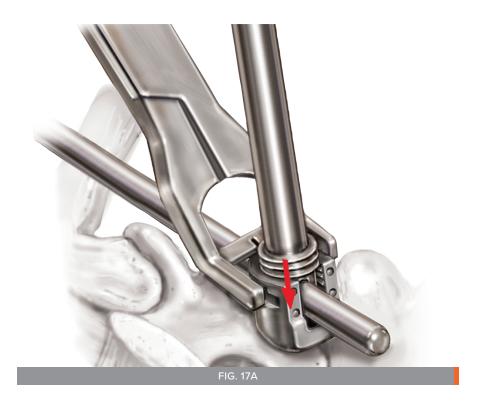
Avoid applying unnecessary lateral bending or rotational force to rod inserter.



STEP 17. ROD REDUCTION

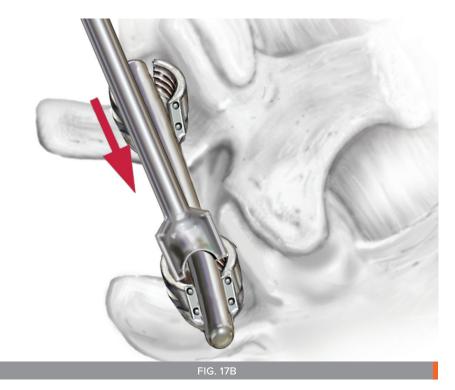
Rocker (52-1251)

Attach rocker to pedicle screw body and lever rod until seated in the pedicle screw (FIG. 17A).



Rod Pusher (52-1050)

Position rod pusher tip on rod and apply axial force until rod is seated in pedicle screw body (FIG. 17B).



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 excess 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.



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 counterclockwise 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 (FIG. 17D).

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. 17D–17E).

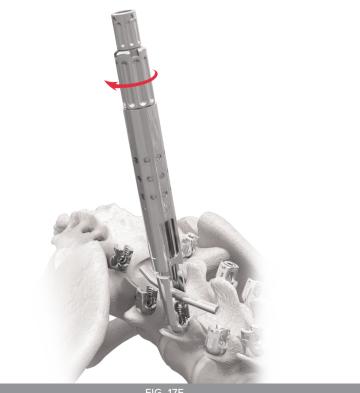


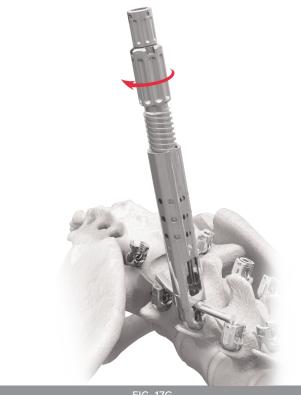


CAUTION

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 (FIG. 17F–17G).





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. 17H).

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. 17I) after complete reduction, simply turn the drive knob counterclockwise past the staband-grab position and the Tubular Reducer will lift off the modular screw body.





FIG. 171

STEP 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 (FIG. 18).



STEP 19. ROD MANIPULATIONS

OPTION A: *In-situ* Rod Benders (52-1070, 52-1071)

Position the *in-situ* rod benders on rod. Gently push rod benders together to create a bend in the rod in the sagittal plane and increase rod lordosis (FIG. 19A).

NOTE

For more complex coronal plane deformities, the use of Coronal Benders (51-1475, 51-1476) will be needed. Available in the Thoracic Fixation Module from the Firebird Deformity Correction System.



FIG. 19A

OPTION B: Rod Grippers (51-480)

Attach rod gripper to rod and apply rotational force to adjust rod orientation prior to fixation (FIG. 19B).



STEP 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 retighten 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.



IG. 20

STEP 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-lb. The torque limiting handle will reach its maximum torque and release at 100 in-lb.

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.

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 clockwise for distraction.

NOTE

Applying too much compression or distraction force to screws may result in pedicle fracture.



FIG. 21

Ratcheting T-Handle (52-1011) 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. 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.

The Mono-Axial Screw Driver can be utilized to remove the screws.

For set screw removal from multi-axial screw, mono-axial screw, or any other connector, use Set Screw Driver (52-1061) inserted into Ratcheting T-Handle (52-1011). It is recommended to use the Counter Torque Wrench (52-1765) to avoid stressing the pedicle.

For multi-axial screw removal, use Multi-Axial Adjustment Driver (52-1339) inserted into Ratcheting T-Handle (52-1011).

For cross connector removal, use Driver (HD2011094) and Extension (EX103128) inserted into Handle (MP204000-J or TR211000-J). These are available in the Evolution-TL kit.

REDUCTION HEAD TECHNIQUE

FIREBIRD REDUCTION IMPLANT/ INSTRUMENT KIT (44-9050)

The following section demonstrates the procedure for reduction head technique

STEP 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. 01).



FIG. 01

STEP 2. ROD PLACEMENT

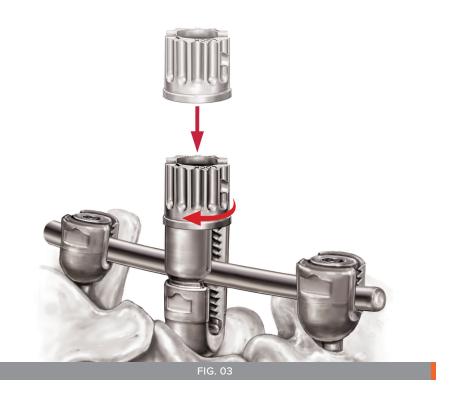
After placing the rod into the saddles, insert set screws into the screws cephalad and caudal to the reduction target. Tighten all set screws caudal to the reduction screw with the torque wrench and counter torque wrench and leave the set screws cephalad of the reduction loose. The opposite approach is equally functional (FIG. 02).



FIG. 02

STEP 3. ANTI-SPLAY CAP ATTACHMENT

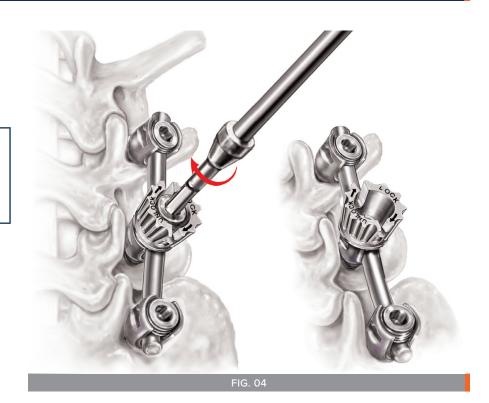
Slide an Anti-Splay Cap (68-0111) down each reduction screw body head until it rests against the rod and rotate clockwise to lock antisplay cap to the reduction head (FIG. 03).



STEP 4. SET SCREW PLACEMENT

Introduce a set screw into each reduction screw body. Advance the set screws in unison or backand-forth from one set screw to the other (FIG. 04).

> **NOTE** Do not remove the antisplay caps until all tabs are removed.



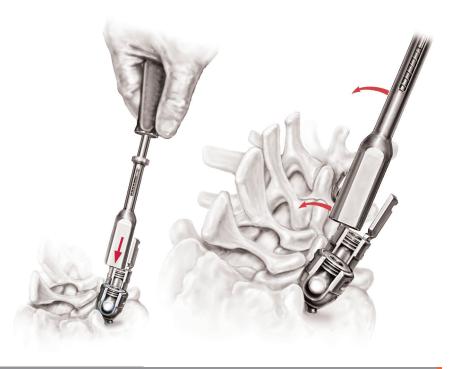
STEP 5A. ANTI-SPLAY CAP REMOVAL

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).



STEP 5B. TAB REMOVAL

Once the anti-splay cap has been removed, the tabs can then be broken using the Tab Removal Tool (61-040**0**) (FIG. 05B).



STEP 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. 05C).

Repeat step 5 for the remaining tabs.



IG. 05C

STEP 6. 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-lb. The torque limiting handle will reach its maximum torque and release at 100 in-lb.

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. 06

ORDERING INFORMATION

FIREBIRD[®] | OPERATIVE TECHNIQUE

INSTRUMENTATION FIREBIRD® INSTRUMENT CASE 1: 44-0060



Ratcheting Handle, Straight, Small

PN 52-1013 QTY 2



INSTRUMENTATION FIREBIRD® INSTRUMENT CASE 1: 44-0060



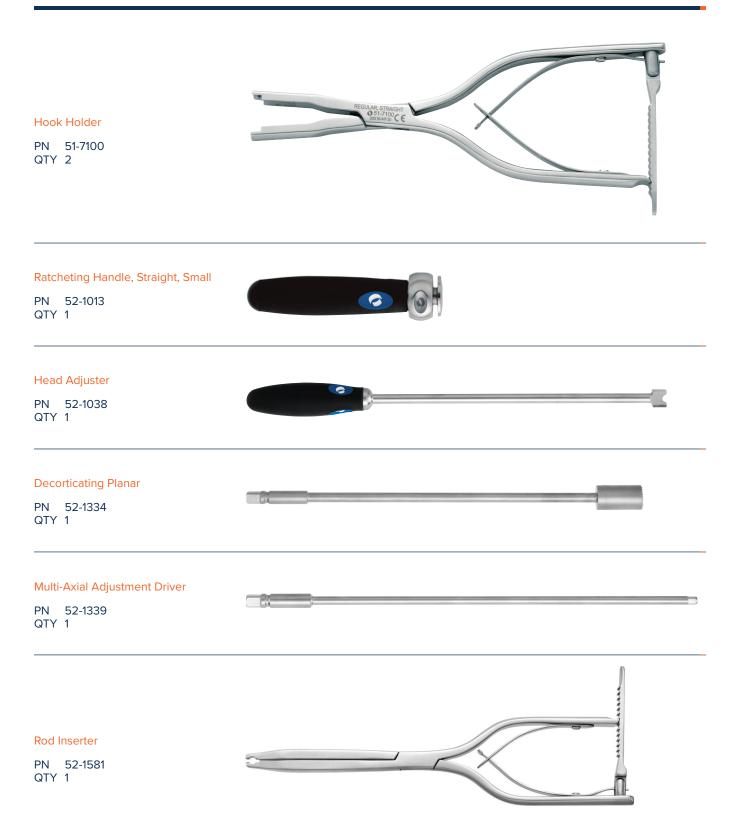
INSTRUMENTATION FIREBIRD® INSTRUMENT CASE 1: 44-0060



Screw Template

PN 52-1308 QTY 1

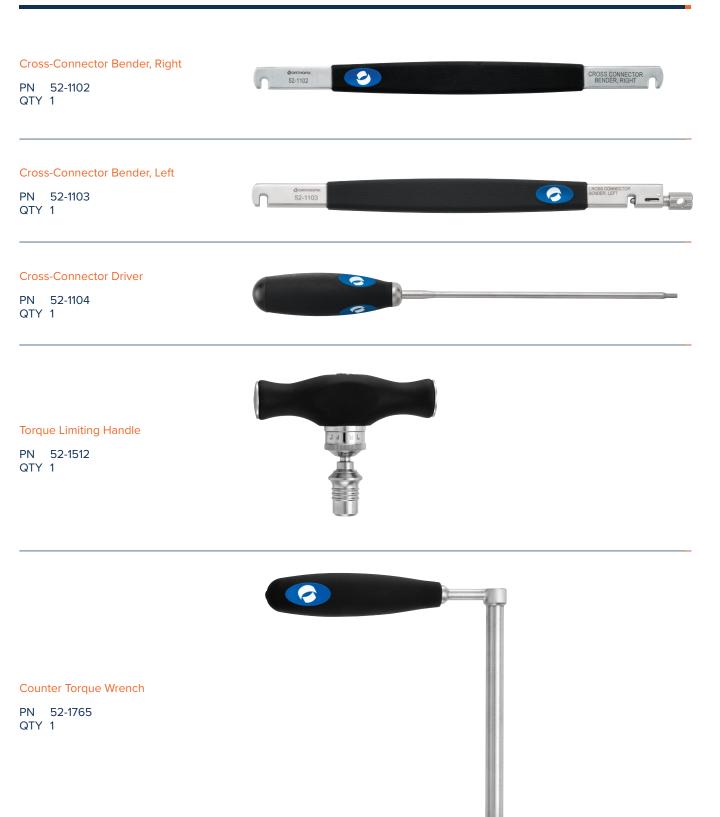
INSTRUMENTATION FIREBIRD® INSTRUMENT CASE 2: 44-0070



INSTRUMENTATION FIREBIRD® INSTRUMENT CASE 2: 44-0070



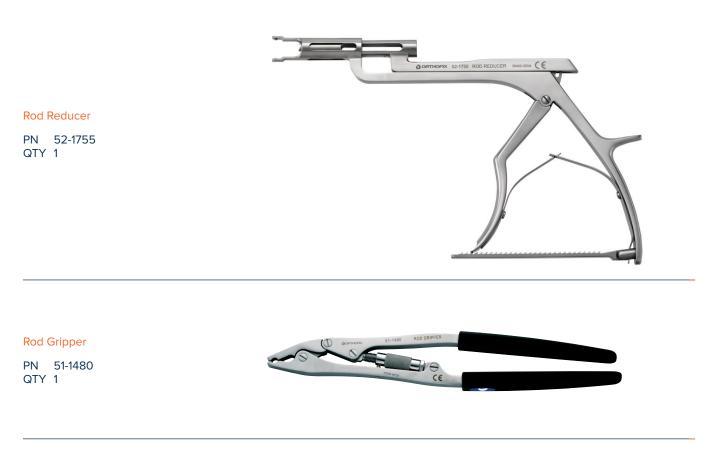
INSTRUMENTATION FIREBIRD® INSTRUMENT CASE 2: 44-0070



INSTRUMENTATION FIREBIRD® INSTRUMENT CASE 3: 44-0080



INSTRUMENTATION FIREBIRD® INSTRUMENT CASE 3: 44-0080

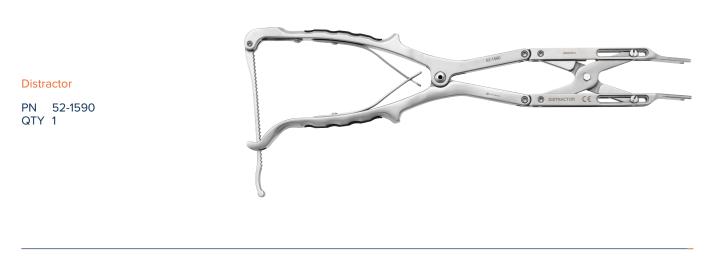


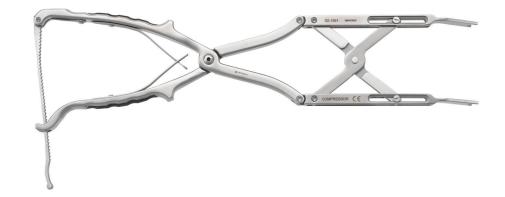
In-Situ Rod Bender

PN 52-1070 (Right) QTY 1

PN 52-1071 (Left) QTY 1

INSTRUMENTATION FIREBIRD® INSTRUMENT CASE 3: 44-0080





Compressor

PN 52-1591 QTY 1

INSTRUMENTATION OPTIONAL

Pin Cutter

PN 55-1041

Bone Tap, Monolithic

IMAGES NOT AVAILABLE

TRAY CONFIGURATION FIREBIRD® INSTRUMENT CASE 1



44-0060

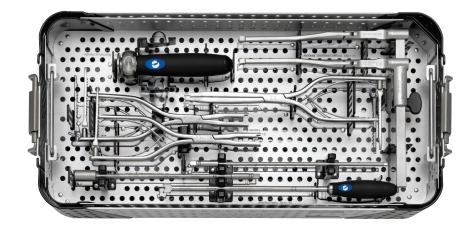
Tray 1, Level 1



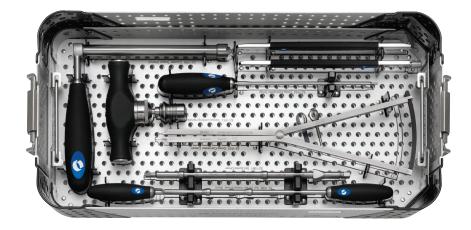
44-0060

Tray 1, Level 2

TRAY CONFIGURATION FIREBIRD® INSTRUMENT CASE 2



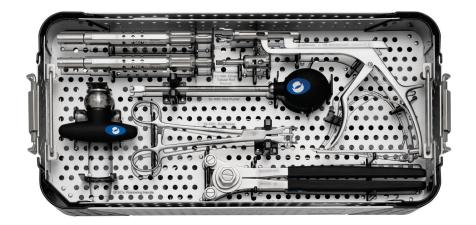
44-0070 Tray 2, Level 1

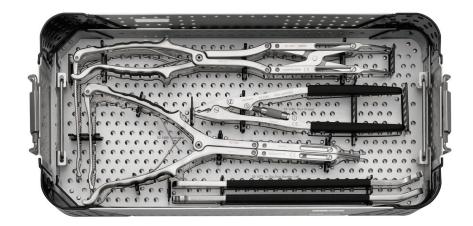


44-0070

Tray 2, Level 2

TRAY CONFIGURATION FIREBIRD® INSTRUMENT CASE 3





44-0080

Tray 3, Level 1

44-0080

Tray 3, Level 2



ORTHOFIX[®] SeaSpine



Please visit Orthofix.com/IFU for full information on indications for use, contraindications, warnings, precautions, adverse reactions, and sterilization.

Orthofix

3451 Plano Parkway Lewisville, Texas 75056-9453 USA tel 1.214.937.3199 | fax 1.888.298.5700 weв www.orthofix.com

EC REP Medical Device Safety Services (MDSS): Schiffgraben 41

30175, Hannover Germany tel +49 511 6262 8630 web www.mdss.com



Australian Sponsor Emergo Australia Level 20, Tower II Darling Park 201 Sussex Street

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician. Proper surgical procedure is the responsibility of the medical professional. Operative techniques are furnished as an informative guideline. Each surgeon must evaluate the appropriateness of a technique based on his or her personal medical credentials and experience.

Orthofix products or services referenced herein are trademarks or registered trademarks of Orthofix Medical Inc. and its group of companies. Any rights not expressly granted herein are reserved. OP-44-9902-US Rev AC | FB-2202 © Orthofix Holdings, Inc. 11/2023.