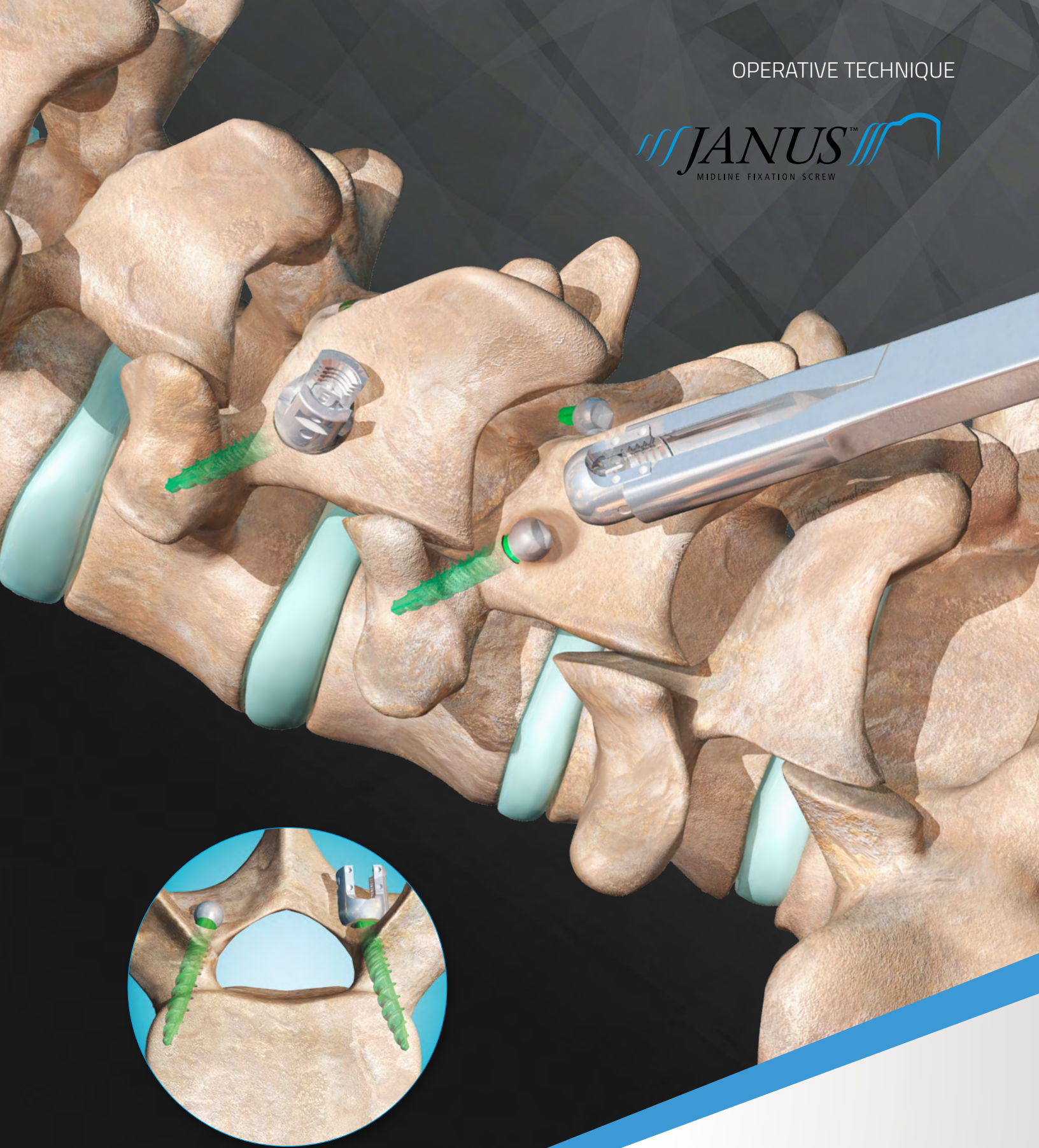


OPERATIVE TECHNIQUE

JANUS™
MIDLINE FIXATION SCREW



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INTRODUCTION

As an addition to the Firebird® Spinal Fixation System, the JANUS® Midline Fixation Screw from Orthofix provides surgeons with the option of a midline approach.

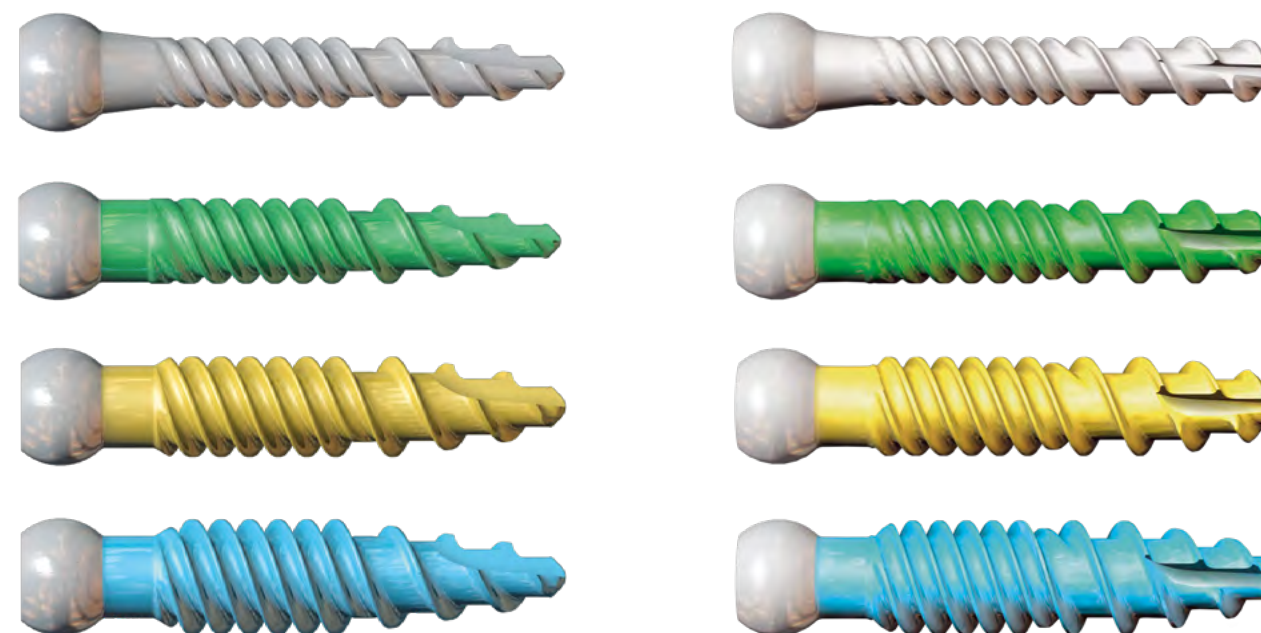
The JANUS Midline Fixation Screw is designed to achieve more cortical bone purchase in the medial to lateral trajectory when compared to traditional pedicle screws. With its modular screw design, maximized visualization is possible when working in a smaller midline incision or minimally invasive surgical approach.



JANUS Midline Fixation Screw is available in both non-cannulated and cannulated versions.

Non-Cannulated

Cannulated



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.



1. ACCESS

A posterior midline incision is made followed by a standard posterior midline approach and placement of common retractors to maintain exposure. The approach is extended to identify the lateral border of the facet and the lateral edge of the pars. In cephalad-caudal direction the exposure is to the mid-facet for the cephalad level and to the mid-lamina for the caudal level. (Fig. 1)

NOTE: When using the JANUS cannulated screw in an MIS procedure, refer to the Phoenix Minimally Invasive Spinal Fixation System Operative Technique.

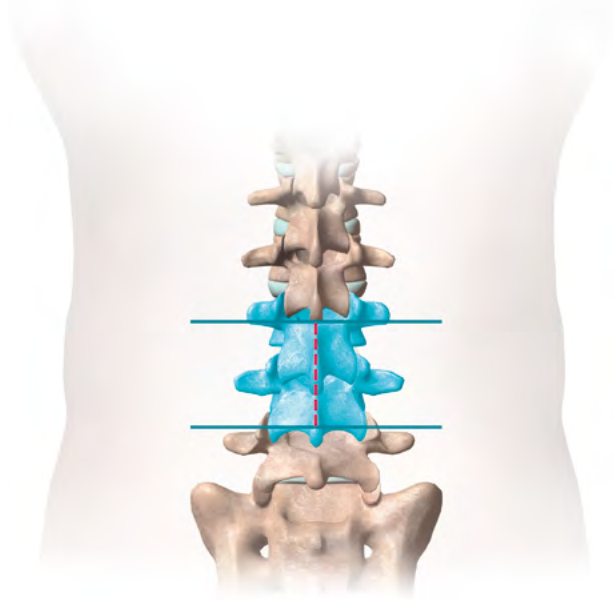


Fig. 1

2. IDENTIFICATION OF ENTRY POINT

Proper entry point for the JANUS Midline Fixation Screw is at the inferior border of the transverse process and about 3mm to 5mm medial to the lateral edge of the pars (approximately the midpoint of the inferior facet of the level above). This position allows the starting point to be superior to the neuroforamen. Obtain an AP image to confirm the entry point is the medial border of the pedicle at a 7 o'clock position for the right pedicle, and a 5 o'clock position for the left pedicle. (Fig. 2)

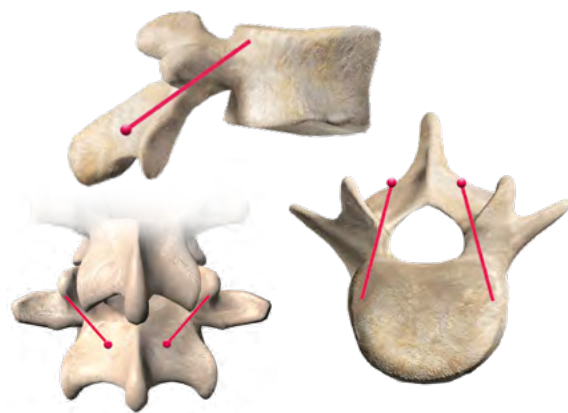


Fig. 2

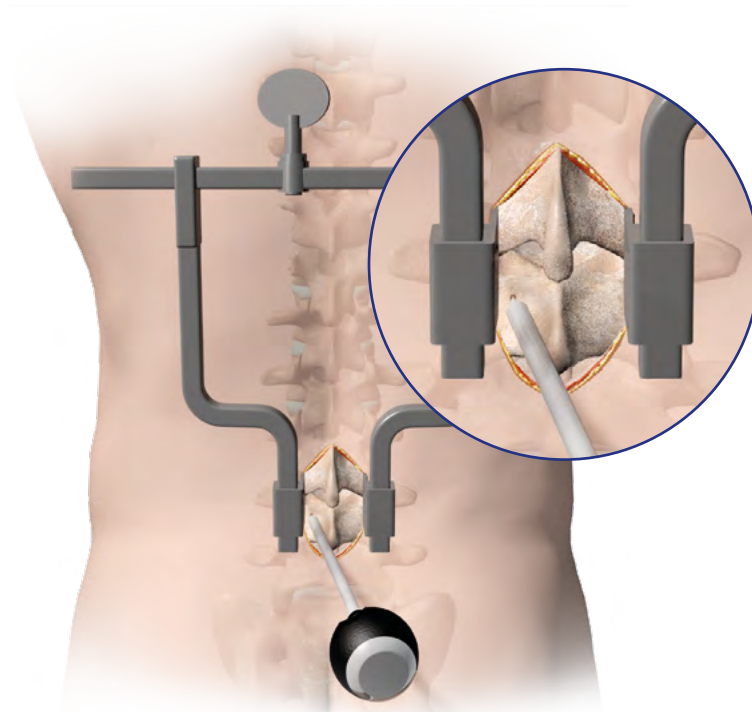


Fig. 2

TRAJECTORY FOR CORTICAL CANCELLOUS SCREW PLACEMENT

Move the C-arm to a lateral position, aim and advance the bone probe to the posterior 1/3 or mid portion of the superior endplate, while aiming approximately 15-20 degrees medial to lateral. The result is an acute trajectory above the neuroforamen and positioned away from the central canal and the exiting nerve root. Note that the sagittal plane inclination of the probe should be at the greatest angle in the caudal-to-cephalad direction.

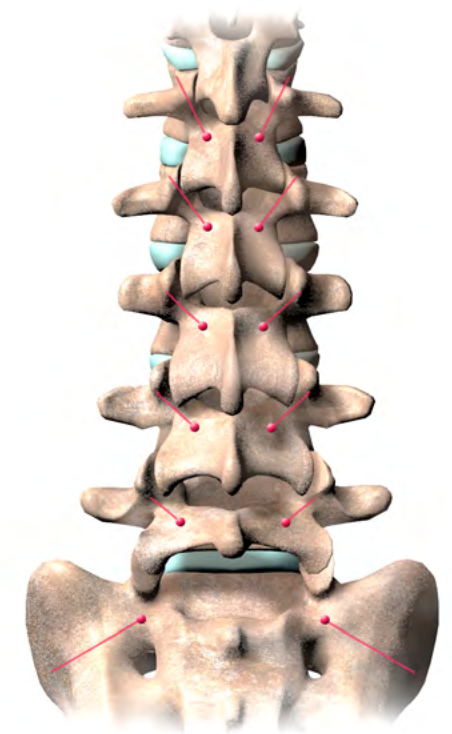


Fig. 3a

3. SCREW STARTING POINTS

Use modular screws for the midline approach indicated by the red lines. (Figs. 3a and 3b)

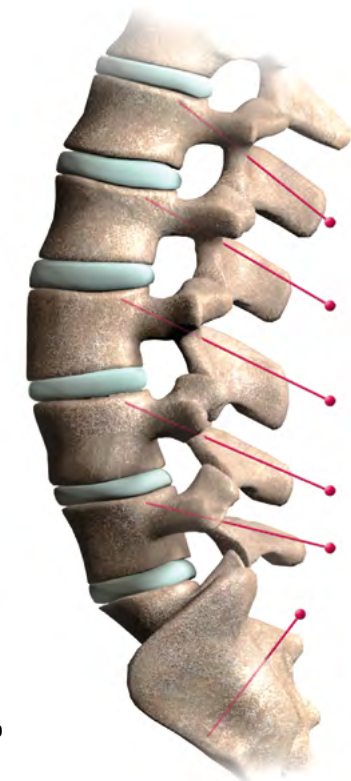


Fig. 3b

4. BONE AWL

(52-1001) Penetrate the cortex of the bone with the bone awl to create a pilot hole at the entry point. **(Fig. 4)**

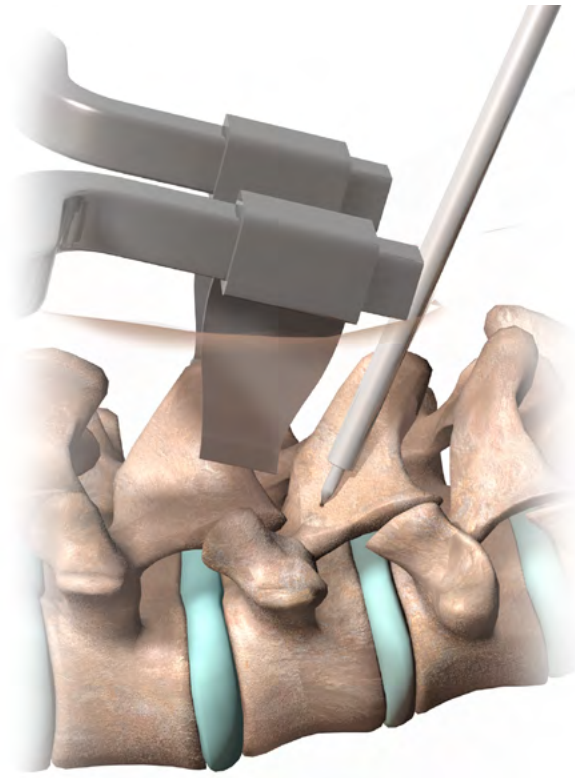


Fig. 4

5. BONE PROBE

(52-1002 / 52-1003) Aim for the posterior 1/3 or mid portion of the superior endplate in the sagittal plane, while aiming approximately 15-20 degrees medial to lateral. **(Fig. 5)**



Fig. 5

6. DRILLING

(36-1124 / 36-1125 / 36-1126 / 36-1127)

Use the drill that corresponds to the selected bone screw diameter. The proximal end of the drill shaft has a colored band that corresponds to the diameter of the screw. Use the A/O quick connect feature on the drill to connect the Modular Handle (69-1030). Insert the drill into the Drill Guide (36-1012). Prior to start of drilling, ensure that the tip of the Drill is in the pilot hole created by the Awl. The drill should be advanced slowly and controlled while using irrigation to prevent bone injury. Aim for the posterior 1/3 or mid portion of the superior endplate in the sagittal plane, while aiming approximately 15-20 degrees medial to lateral. The endplate should not be breached. The drill is capable of drilling 28.5mm deep holes. **(Fig. 6)**

Diameter	Screw Color	Drill Color	Tap Color
4.5mm	Silver	Silver	Silver
5.5mm	Green	Green	Green
6.5mm	Gold	Gold	Gold
7.5mm	Blue	Blue	Blue

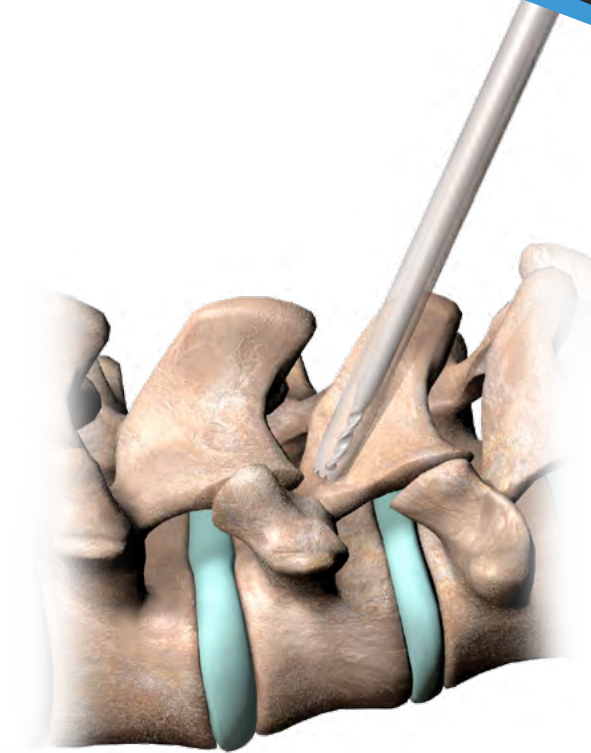


Fig. 6

7. SOUNDER

(52-1004 Small / 52-1005 Large) Use the sounder to confirm the existence of bone along the walls of the screw trajectory. Choose the appropriate tip and internally palpate to ensure the walls are not perforated. **(Fig. 7)**

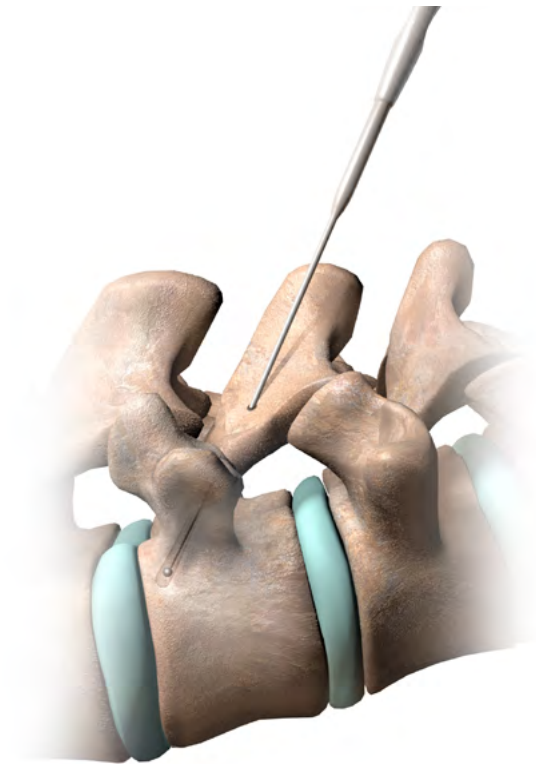


Fig. 7

8. X-RAY MARKERS

(55-1006 Right / 52-1007 Left) Use the right and left x-ray markers to confirm trajectory under fluoroscopy prior to screw insertion. **(Fig. 8)**

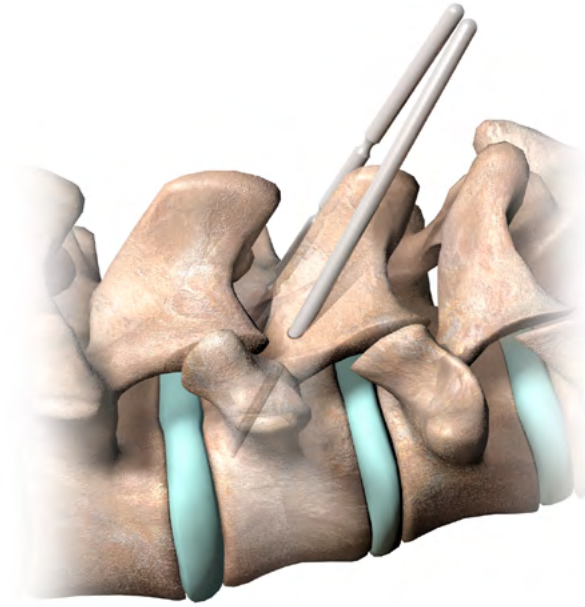


Fig. 8

9. SCREW SIZING TEMPLATE

Use the Screw Sizing Template (52-1308) to verify screw diameter and length of the JANUS Midline Fixation Screw prior to insertion. **(Fig. 9)**



Fig. 9

10. TAP

Tap the pilot hole with the same size bone tap as the final screw diameter and advance to the superior endplate. Tap to the appropriate depth based on the length of the JANUS Midline Fixation Screw to be implanted for optimal screw purchase, using the 5 millimeter increment markings on the tap as a guide. Do not violate the endplate.

Select the Bone Tap (36-XXXX) that matches the bone screw diameter that will be used. The Bone Tap dimensions are line to line (one to one) with the bone screw dimensions. The bone tap only includes the bone screw cancellous thread form. Use Bone Tap (36-) to tap the pilot hole and continue advancing the bone tap to endplate of the vertebral body. Use the 5mm markings along the length of the bone tap shaft to determine how deep the tip of the bone tap is advancing. **(Fig. 10)**

NOTE: Tapping is required prior to inserting a JANUS Midline Fixation Screw, the optional JANUS Cortical Bone Tap (36-XXXX) must be used. Firebird and Phoenix® Taps are designed with a different thread pitch. To reduce the risk of screw pullout, it is not recommended to use a Firebird or Phoenix Tap to prepare the hole for a JANUS Midline Fixation Screw insertion.

NOTE: To attach the Ratcheting Handle, T-Handle 52-1011) or Ratcheting Handle Straight, Small (52-1013) to the modular taps, retract the shaft connector sleeve and insert the square-drive shaft end of tap into the handle connector, and release shaft connector sleeve. To disengage the tap from the handle, retract the shaft connector sleeve and firmly tug on the instrument shaft.

NOTE: Ensure that the Tap is fully inserted and seated inside the Straight or Ratcheting T-handle, prior to the application of torque. Inadequate seating may create a binding condition with the handle, after torque is applied. Proper connection of the shaft with the handle can be confirmed by gently tugging on the shaft

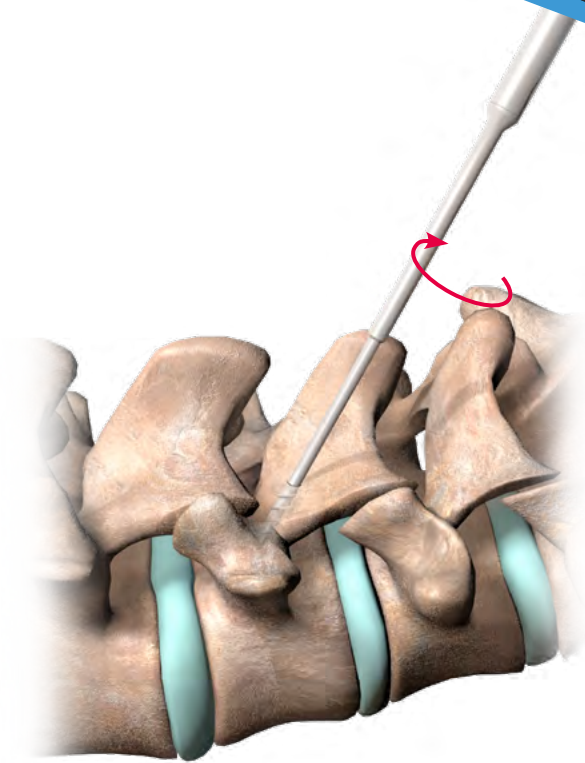


Fig. 10

11. SCREW INSERTION

Midline Screw Driver (36-1834) Insert the self-retaining driver completely into the JANUS screw.

Insert the JANUS screw until it is positioned at the posterior 1/3 or mid portion of the superior endplate. The screw should not perforate the endplate. The spherical screw head should be left slightly proud to avoid damage to the facet joint. To disengage the Midline Screw driver, lift the screw driver until it separates from the JANUS screw.

NOTE: Do not apply levering force to driver during screw insertion as this can result in missed trajectory of screw or vertebral fractures.

NOTE: If the screw insertion site is not prepared by drilling and tapping, there is an increased chance of toggle between the bone screw and the Modular Screw Driver (36-1834) that could affect bone screw trajectory.

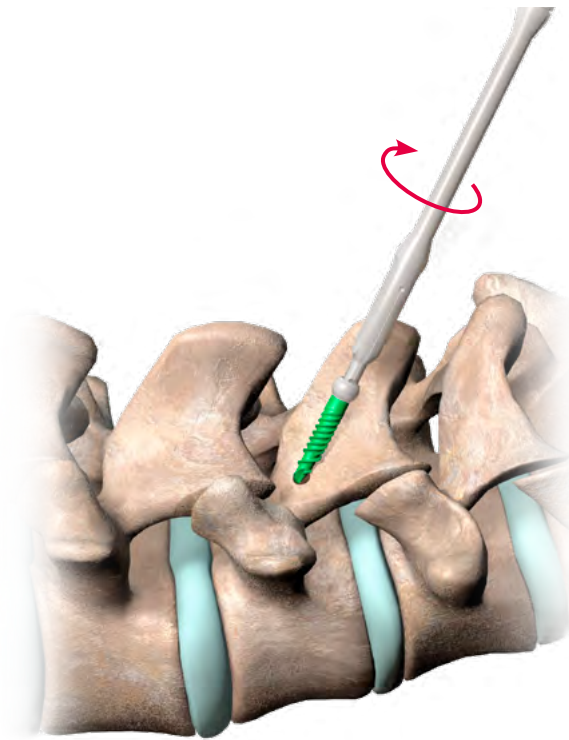


Fig. 11

12. DECORTICATION

Decorticating Planer (52-1334)

After placement of the modular JANUS Midline Fixation Screw, place the decorticating planer over the spherical head of the bone screw. Rotate the planer surface clockwise and counterclockwise to decorticate bone and allow for proper seating of modular body providing full range of motion. (Fig. 12)

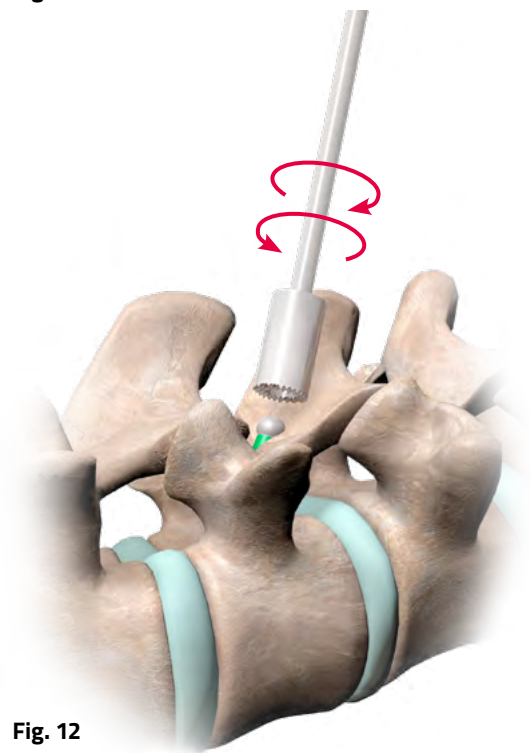


Fig. 12

13. SCREW BODY OPTIONS

Top-Loading (44-2101) Insert the rod from a top orientation 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. (Fig. 13)



Fig. 13

14. MODULAR BODY ATTACHMENT

After placement of the modular JANUS Midline Fixation Screw, attach the appropriate modular body to the Holder (51-7100) 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 JANUS Midline Fixation Screw. 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. 14)

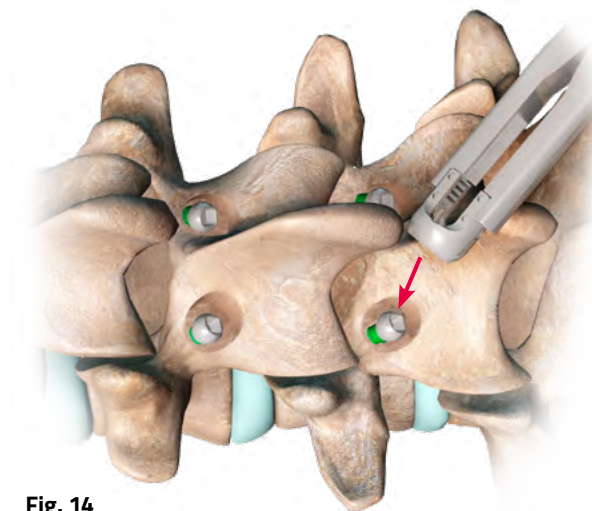


Fig. 14

15. BODY ALIGNMENT

Head Adjuster (52-1038) Use the head adjuster to align the top opening bodies of the multi-axial screw prior to rod insertion.

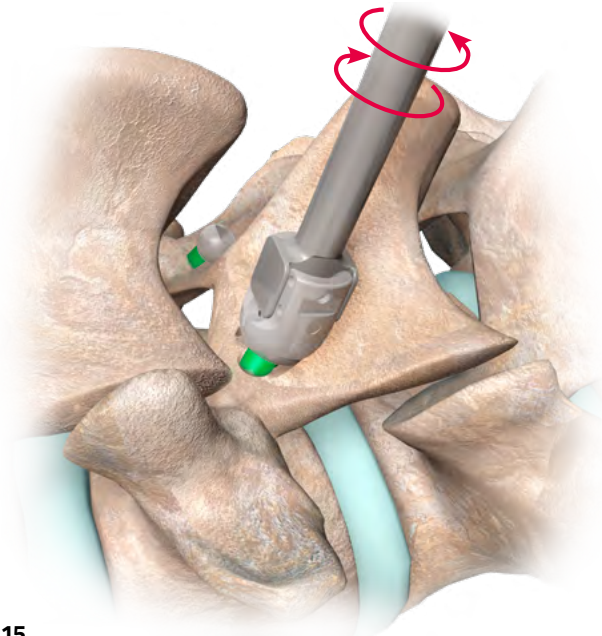


Fig. 15

16. ADJUSTMENT DRIVER

Multi-Axial Adjustment Driver (52-1339) Use the multi-axial adjustment driver to adjust the sagittal height of the screws prior to rod insertion. (Fig. 16)

NOTE: This instrument can assist in restoring mobility of the multi-axial bodies if screw has been driven too deep. (Fig. 16)

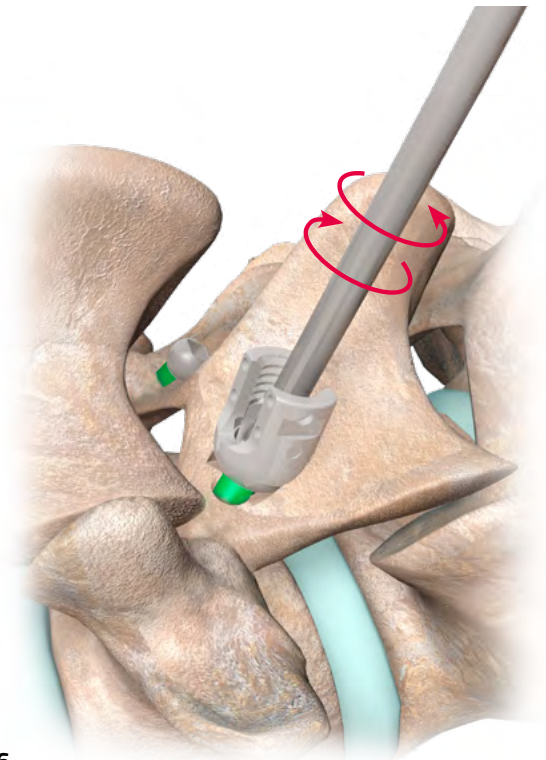


Fig. 16

17. 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 Spinal Fixation System implants. (Fig. 17)

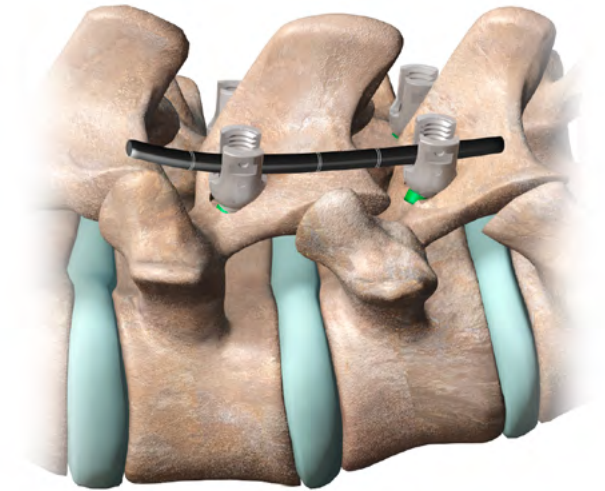


Fig. 17

18. 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. 18)

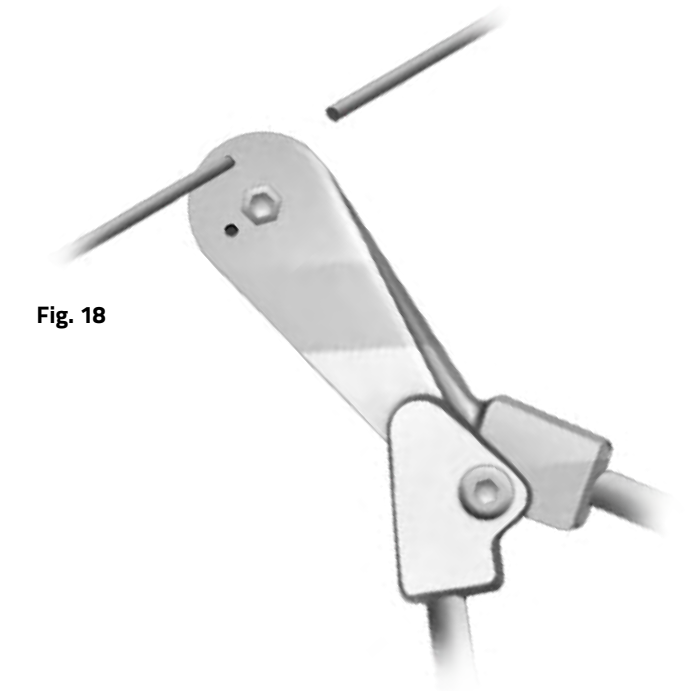


Fig. 18

19. ROD CONTOURING

Rod Bender (52-1046) Utilizing the rod bender, create the correct contour, referencing the rod template as a guide. See step 17 for determining rod length.

WARNING: 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. **(Fig. 19)**



Fig. 19

20. 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 inserter.

NOTE: Ensure the rod seating area is clear of any bony/tissue interferences before attempting to reduce the rod. **(Fig. 20)**

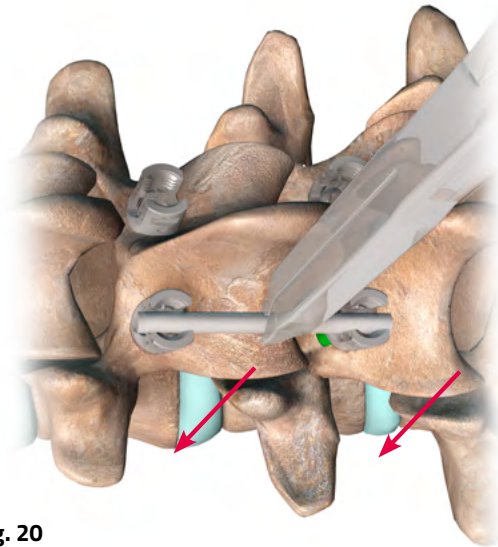


Fig. 20

21. ROD ROCKER

Rod Rocker (52-1251) Attach rocker to screw body and lever rod until seated in the screw.

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. **(Fig. 21)**

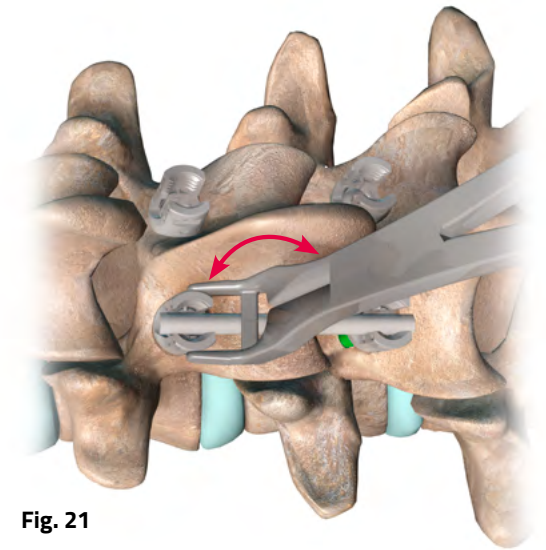


Fig. 21

22A. ROD PUSHER

Rod Pusher (52-1050) Position rod pusher tip on rod and apply axial force until rod is seated in screw body. **(Fig. 22a)**

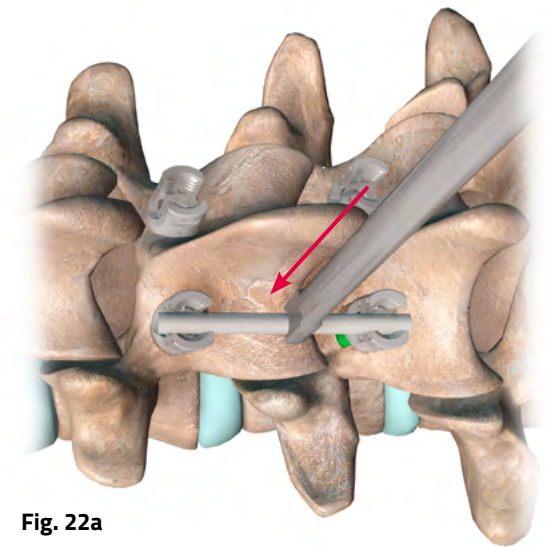


Fig. 22a

22B. ROD REDUCER

Rod Reducer (52-1755) Slide rod reducer tip over the screw body and seat pins into indents. Take care to align inner shaft with rod prior to reduction. **(Fig. 22b)**

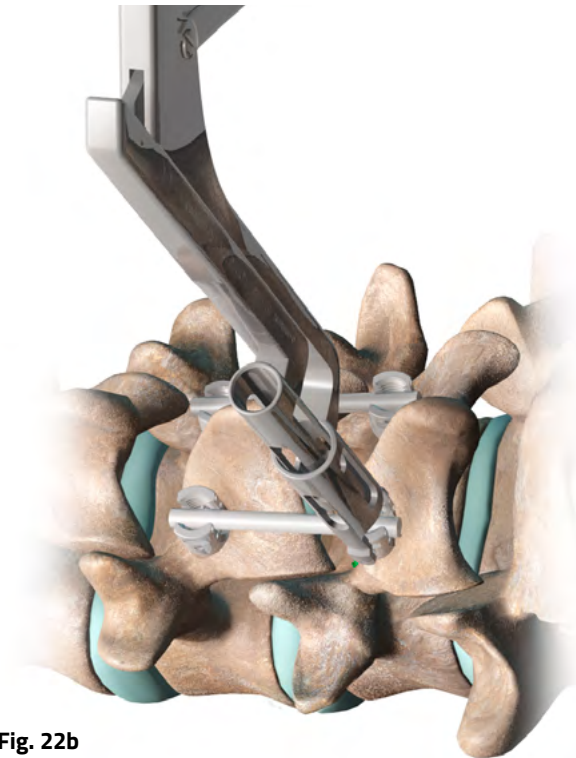


Fig. 22b

23. FINAL TIGHTENING

Counter Torque Wrench (52-1765) Set Screw Driver (52-1061) Torque Limiting Handle (52-1512)

Position the counter torque wrench over the 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. 23)**

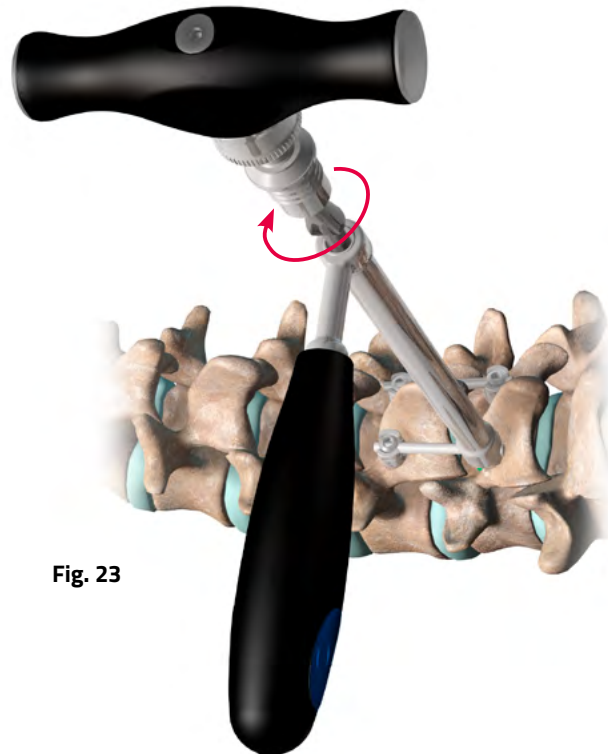


Fig. 23

24. REMOVAL

Set Screw Driver (52-1061) Counter Torque Wrench (52-1765) Multi-Axial Adjustment Driver (52-1339)

In order to remove the JANUS Midline Fixation Screw, 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. **(Fig. 24)**

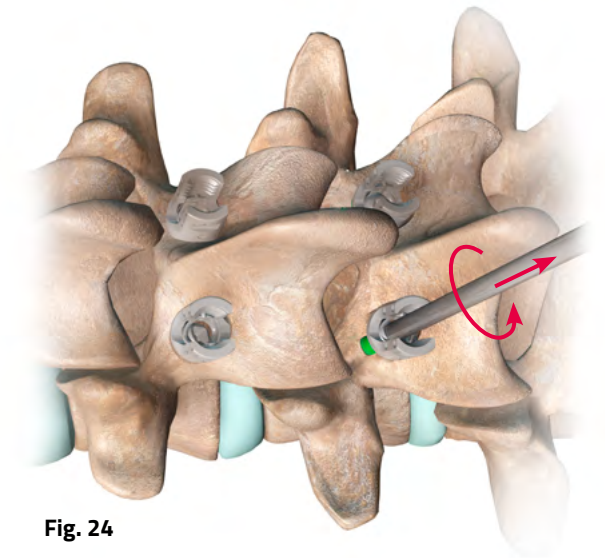


Fig. 24

If Firebird Spinal Fixation System implants needs removal:

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.

If Firebird NXG Spinal Fixation System implants needs removal:





For set screw removal from multi-axial screw or any other connector, use Set Screw Driver (36-1161) inserted into Ratcheting T-Handle (36-1011). It is recommended to use the Counter Torque Wrench (36-1765) to avoid stressing the pedicle.

For multi-axial screw removal, use Multi-Axial Adjustment Driver (52-1339) inserted into Ratcheting T-Handle (36-1011).





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.

INSTRUMENTS





Drills

	Part #	Description
	36-1124	4.5mm
	36-1125	5.5mm
	36-1126	6.5mm
	36-1127	7.5mm


Non-cannulated Cortical Bone Tap, Modular)

	Part #	Description
	36-1224	4.5mm
	36-1225	5.5mm
	36-1226	6.5mm
	36-1227	7.5mm



Cannulated Cortical Bone Tap, Modular)

	Part #	Description
	36-1424	4.5mm
	36-1425	5.5mm
	36-1426	6.5mm
	36-1427	7.5mm

Handle)

	Part #	Description
	69-1030	Modular Handle

Drill Guide

	Part #	Description
	36-1012	Drill Guide
	36-1834	Midline Screw Driver

36-7200 Instruments



Top Level

Bottom Level

IMPORTANT ORDERING INFORMATION: the instrument case and JANUS screw caddies have individual product numbers and must be ordered at the same time. The JANUS cannulated and non-cannulated screw caddies are not included in the instrument case during shipment. The JANUS screw caddies should be placed inside the instrument case for the procedure, cleaning and sterilization.

IMPLANTS

36-9100 Non-Cannulated Implant Caddy

Part #	Description	Qty	Availability
36-2425	4.5mm x 25mm	6	Standard
36-2430	4.5mm x 30mm	6	Standard
36-2435	4.5mm x 35mm	6	Standard
36-2440	4.5mm x 40mm	6	Standard
36-2445	4.5mm x 45mm	6	Standard
36-2525	5.5mm x 25mm	6	Standard
36-2530	5.5mm x 30mm	6	Standard
36-2535	5.5mm x 35mm	6	Standard
36-2540	5.5mm x 40mm	6	Standard
36-2545	5.5mm x 45mm	6	Standard
36-2625	6.5mm x 25mm	4	Standard
36-2630	6.5mm x 30mm	4	Standard
36-2635	6.5mm x 35mm	4	Standard
36-2640	6.5mm x 40mm	4	Standard
36-2645	6.5mm x 45mm	4	Standard

Optional Non-Cannulated Implants

Part #	Description	Availability
36-2450	4.5mm x 50mm	By request
36-2455	4.5mm x 55mm	By request
36-2460	4.5mm x 60mm	By request
36-2465	4.5mm x 65mm	By request
36-2550	5.5mm x 50mm	By request
36-2555	5.5mm x 55mm	By request
36-2560	5.5mm x 60mm	By request
36-2565	5.5mm x 65mm	By request
36-2650	6.5mm x 50mm	By request
36-2655	6.5mm x 55mm	By request
36-2660	6.5mm x 60mm	By request
36-2665	6.5mm x 65mm	By request
36-2725	7.5mm x 25mm	By request
36-2730	7.5mm x 30mm	By request
36-2735	7.5mm x 35mm	By request
36-2740	7.5mm x 40mm	By request
36-2745	7.5mm x 45mm	By request
36-2750	7.5mm x 50mm	By request
36-2755	7.5mm x 55mm	By request
36-2760	7.5mm x 60mm	By request
36-2765	7.5mm x 65mm	By request

36-9200 Cannulated Implant Caddy

Part #	Description	Qty	Availability
36-3425	4.5mm x 25mm	6	Standard
36-3430	4.5mm x 30mm	6	Standard
36-3435	4.5mm x 35mm	6	Standard
36-3440	4.5mm x 40mm	6	Standard
36-3445	4.5mm x 45mm	6	Standard
36-3525	5.5mm x 25mm	6	Standard
36-3530	5.5mm x 30mm	6	Standard
36-3535	5.5mm x 35mm	6	Standard
36-3540	5.5mm x 40mm	6	Standard
36-3545	5.5mm x 45mm	6	Standard
36-3625	6.5mm x 25mm	4	Standard
36-3630	6.5mm x 30mm	4	Standard
36-3635	6.5mm x 35mm	4	Standard
36-3640	6.5mm x 40mm	4	Standard
36-3645	6.5mm x 45mm	4	Standard

Optional Cannulated Implants

Part #	Description	Availability
36-3450	4.5mm x 50mm	By request
36-3455	4.5mm x 55mm	By request
36-3460	4.5mm x 60mm	By request
36-3465	4.5mm x 65mm	By request
36-3550	5.5mm x 50mm	By request
36-3555	5.5mm x 55mm	By request
36-3560	5.5mm x 60mm	By request
36-3565	5.5mm x 65mm	By request
36-3650	6.5mm x 50mm	By request
36-3655	6.5mm x 55mm	By request
36-3660	6.5mm x 60mm	By request
36-3665	6.5mm x 65mm	By request
36-3725	7.5mm x 25mm	By request
36-3730	7.5mm x 30mm	By request
36-3735	7.5mm x 35mm	By request
36-3740	7.5mm x 40mm	By request
36-3745	7.5mm x 45mm	By request
36-3750	7.5mm x 50mm	By request
36-3755	7.5mm x 55mm	By request
36-3760	7.5mm x 60mm	By request
36-3765	7.5mm x 65mm	By request

Please refer to the product “Instructions for Use” for full information on indications for use, contraindications, warnings, precautions and adverse reactions at orthofix.com/IFU

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.



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