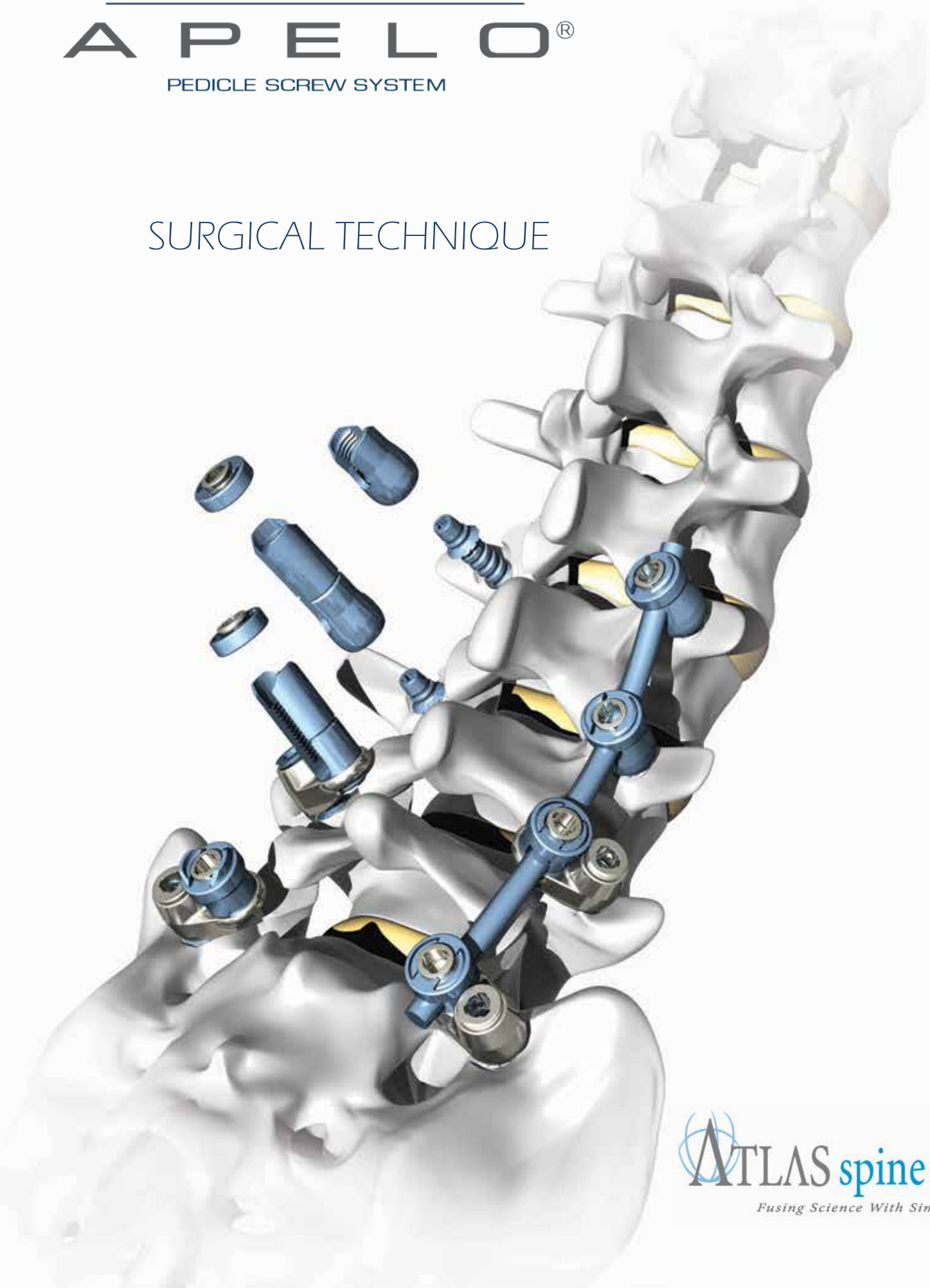
APELO®

PEDICLE SCREW SYSTEM

SURGICAL TECHNIQUE



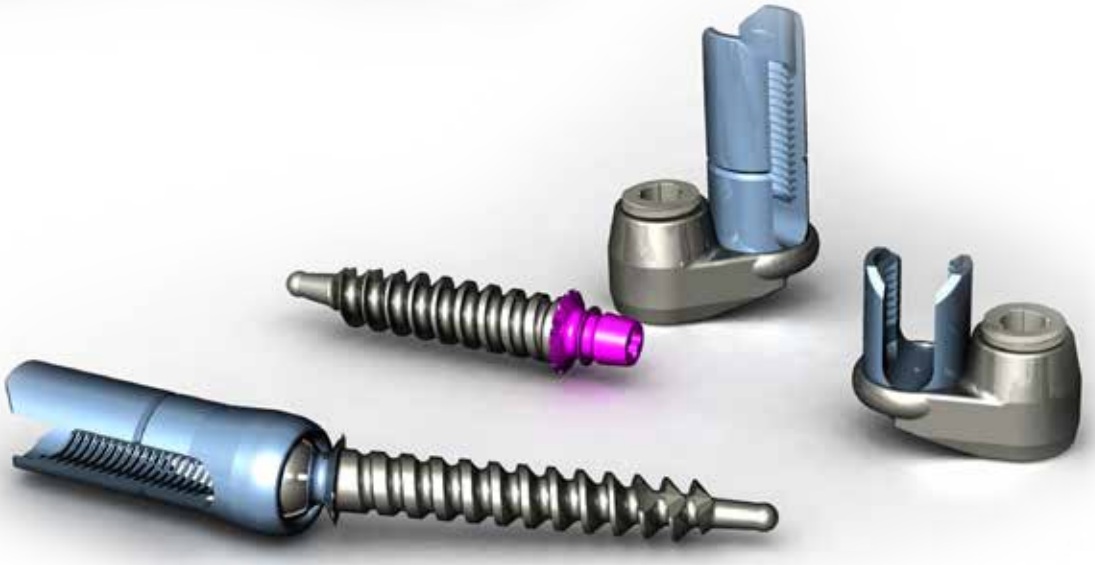
ATLAS spine

Fusing Science With Simplicity

INTRODUCTION

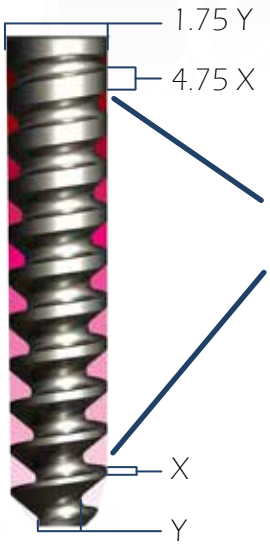
The APELO Pedicle Screw System is a novel modular screw and connector system highlighted by interchangeable poly-axial heads for intra-operative versatility and advanced design features engineered to maximize screw purchase, construct integrity, and simplicity of final assembly.

The design of the system is a result of many years of clinical experience, surgical observation, and consultation with spine surgeons in pursuit of a comprehensive yet easy to use system to address the multiple challenges faced in surgery every day.

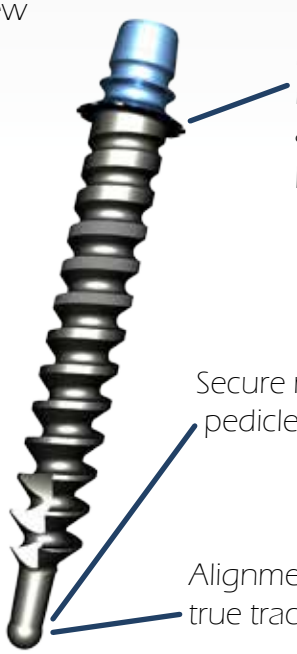


FEATURES AND BENEFITS

Advanced Screw Design:
Unique features increase screw strength, bone purchase and ease of insertion.



Tapered thread crest (X) and tapered minor diameter (Y) increase screw strength and purchase

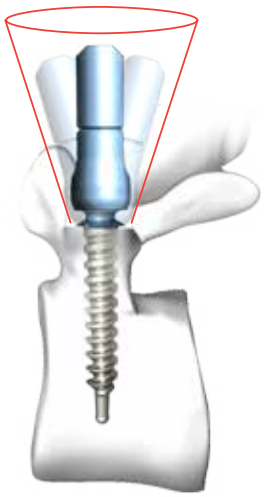


Flange increases lateral strength and provides a positive depth stop

Secure retention of the pedicle opening

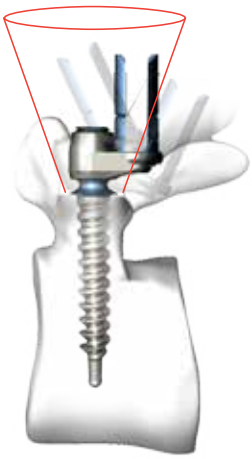
Alignment tip promotes true track insertion

50° of poly-axial freedom

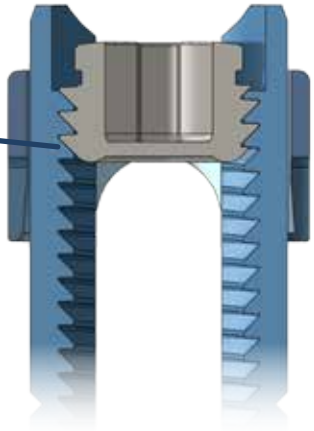


Locking bead deforms against rod to prevent Locking Collar "Back Out"

50° of poly-axial freedom



The integrated 2 in 1 Locking Collar is designed to prevent the "cross threading and head splay" often experienced with single set screw mechanisms



TECH INFORMATION

MODULAR SCREWS

DIMENSIONS	25 mm	30 mm	35 mm	40 mm	45 mm	50 mm	55 mm	60 mm
4.5 mm	X	X	X	X	X			
5.5 mm	X	X	X	X	X			
6.5 mm	X	X	X	X	X	X	X	X
7.5 mm		X	X	X	X	X	X	X
8.5 mm		X	X	X	X	X	X	X

STANDARD HEADS

STANDARD REDUCTION HEAD

STANDARD HEAD

OFFSET HEADS

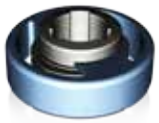
OFFSET REDUCTION HEAD

OFFSET HEAD NON-REDUCTION

LOCKING COLLAR

STANDARD LOCKING COLLAR

OFFSET LOCKING COLLAR



ROD OPTIONS

TYPE	RANGE
Contoured	30 mm - 110 mm in 5 mm increments
Straight	30 mm - 110 mm in 5 mm increments
Uncut Rods	200, 300, 400 and 500 mm

CROSS CONNECTOR OPTIONS

VARIABLE CROSS CONNECTOR

SIZE	RANGE
1	42 -48 mm
2	48 - 54 mm
3	54 - 60 mm
4	60 - 66 mm
5	66 - 72 mm

FIXED CROSS CONNECTOR

20 mm to 42 mm Fixed Cross Connectors in increments of 2

TABLE OF CONTENTS

INSTRUMENT OVERVIEW

SET 1


T-HANDLE
HEAD APPLICATOR
HEAD GROOMING TOOL
HEAD REMOVAL TOOL
MODULAR SCREWDRIVER
TISSUE SLEEVE
FRENCH ROD BENDER
DUAL LOCKING COLLAR STARTER
CURVED ROD HOLDER
ADJUSTMENT DRIVER

SET 2


TORQUE DRIVER
TORQUE LIMITING T-HANDLE
COUNTER TORQUE
COMPRESSOR
COMPRESSOR/ DISTRACTOR TIPS
TAB REMOVAL TOOL
LEFT & RIGHT OFFSET COMPRESSOR TIPS

DISTRACTOR

CAM DRIVER

NUT DRIVER

LEFT & RIGHT OFFSET
DISTRACTOR TIPS

POWER ROD
GRIPPER

LEFT INSITU
BENDER

RIGHT INSITU
BENDER

INSTRUMENTATION APPLICATION

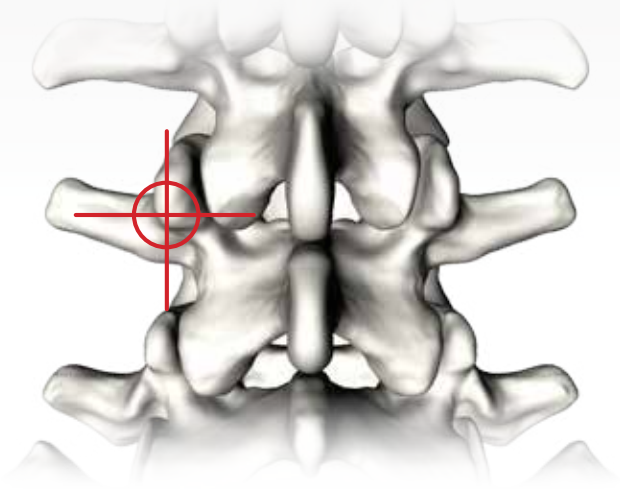


Figure 1

STEP 1: PEDICLE TARGETING

- PEDICLE LOCATION:

Preoperative planning defines the most appropriate implants, as well as the optimal location of where the implants should be inserted. Surgical levels may be verified clinically or radiographically.

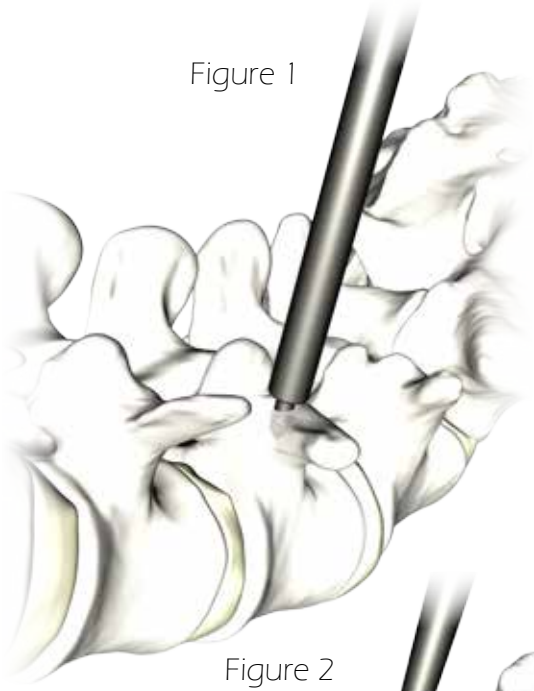


Figure 2

STEP 2: PEDICLE PREPARATION

- INITIAL AWL:

A Starter Awl may be used to break through the cortex of the pedicle. The Starter Awl has a depth stop at 12 mm. (Figure 2).

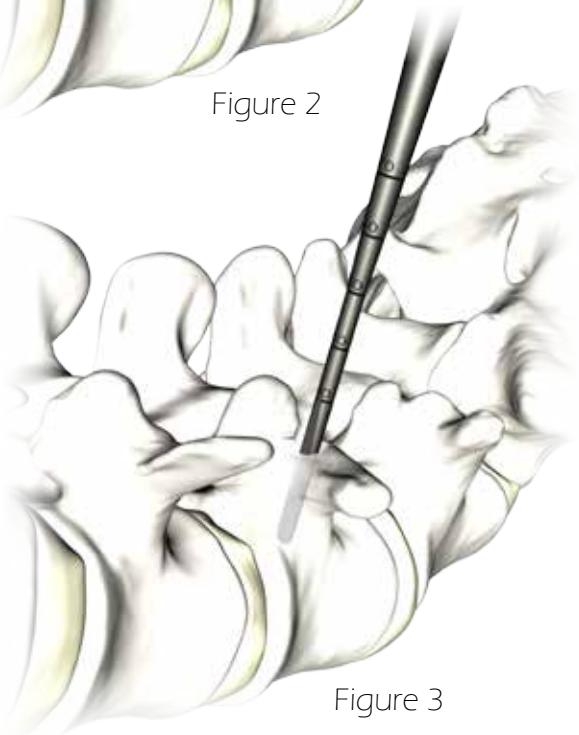


Figure 3

- PEDICLE PROBE INSERTION:

A pathway through the pedicle and into the vertebral body is created by driving the Pedicle Probe anteriorly using a back and forth, twisting motion. The probe is etched at 10mm intervals to indicate the depth to which the probe has been inserted and to help determine proper screw length. (Figure 3).

*Note: It is recommended that fluoroscopic imaging be used during this step.

Figure 4

- PEDICLE MARKER INSERTION:

If the surgeon prefers to prepare multiple pedicles before placing the screws, radiographic pedicle markers are available to serve as placeholders for prepared pedicles. Two different head geometries are available to differentiate between the "right" and "left" markers. (Figure 4).

- TAPPING:

It is suggested the screw hole is prepared with the appropriate Bone Tap before the screw is inserted. Apelo Bone Taps have slightly undersized features to provide bone compaction and firm screw purchase. (Figure 6)

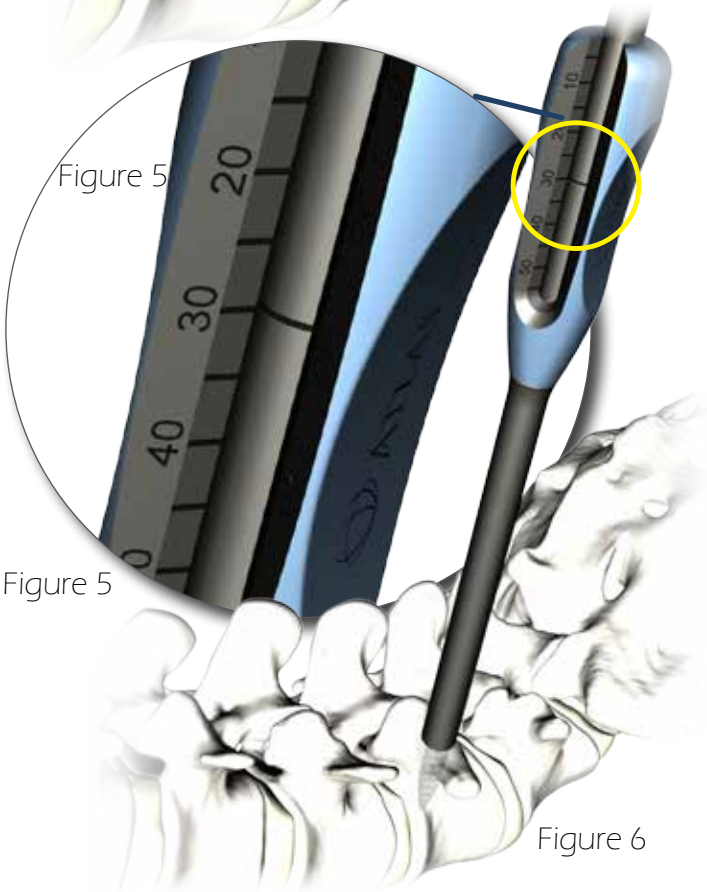


Figure 5

Figure 5

- VERIFYING TAP DEPTH:

It is recommended that the Tap Sleeve be attached to the Bone Tap before use. The Bone Tap and Tap Sleeve are etched to provide the surgeon with a depth indication. Ensure the Tap Sleeve is fully seated against the pedicle for accurate measurements. (Figure 5)

*Note: Since under tapping is built in, the diameter of the final tap used in preparing each screw hole should match the diameter of the screw (i.e. a 5.5mm tap for a 5.5mm screw). In addition, the tap should be advanced to the full length of the screw (i.e. 45mm tap for a 45mm screw). The same principle should apply for a revision surgery of Apelo or other pedicle screw systems. Given the aggressive purchase due to the tapered minor diameter of the Apelo screw, failure to do so can result in fracture of the screwdriver.

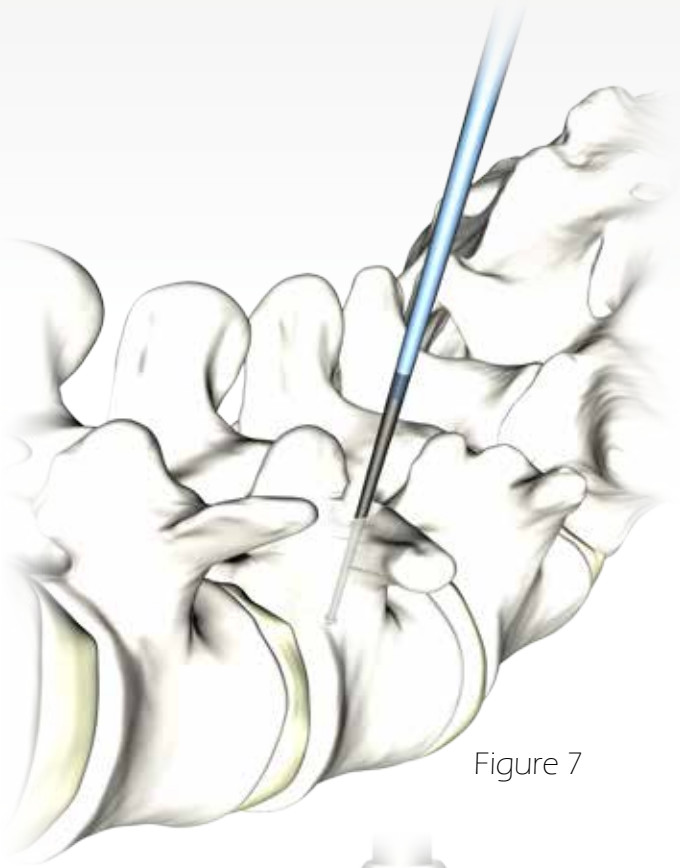


Figure 7

- PROBING:

The prepared pathway may be checked with the Sounding Probe to verify that the walls of the pedicle have not been violated. (Figure 7)

*Note: The etched ring on the Sounding Probe represents a depth of 40mm.

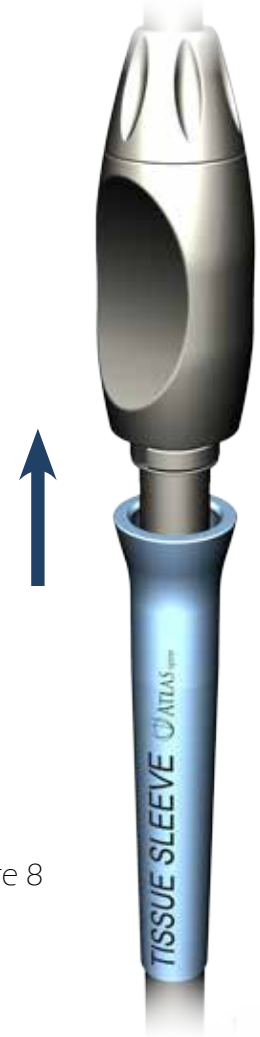


Figure 8

STEP 3: MODULAR SCREW INSERTION

- MODULAR SCREWDRIVER ASSEMBLY:

The blue Tissue Sleeve should be assembled onto the Modular Screwdriver until it is flush with the thumb grip before any screw is loaded. (Figure 8)

Figure 9

- MODULAR SCREWDRIVER - SCREW INTERFACE: Before attempting to load a screw into the Modular Screwdriver, ensure that the thumb grip is rotated counter-clockwise fully to expose the driver and collet. (Figure 9)

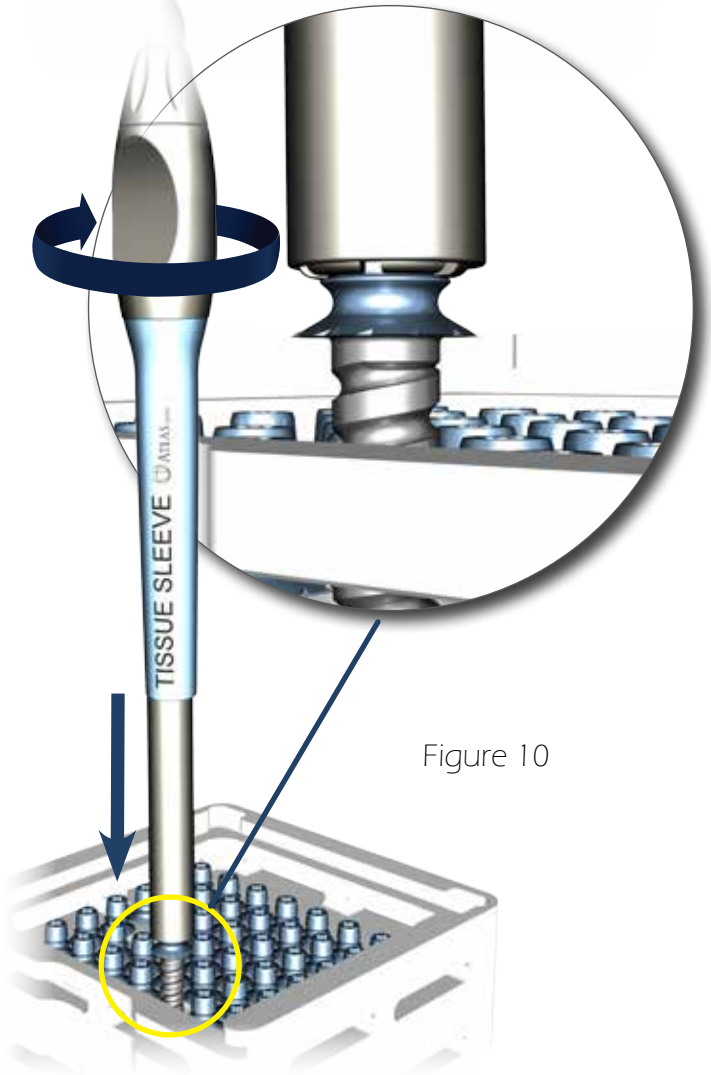


Figure 10

Once the collet is completely inserted over the head of the screw, the thumb grip should be rotated clockwise firmly to capture the screw. Screws may be loaded into the Modular Screwdriver without removing them from the screw caddy. (Figure 10)

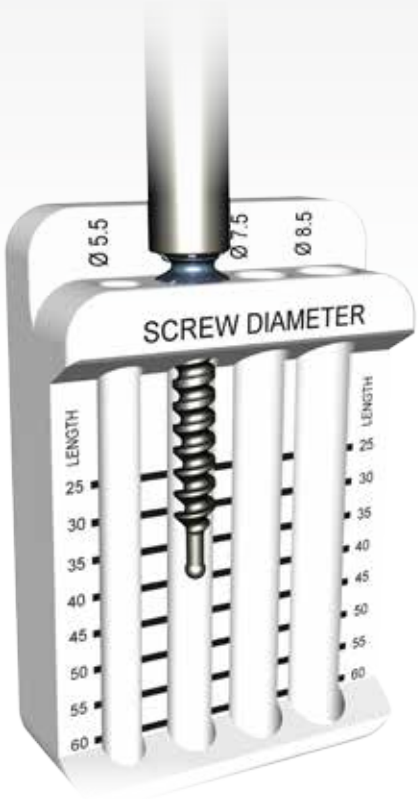


Figure 11

- VERIFY SCREW SIZE:

The Screw Sizing Template may be used to verify both the diameter and length of the screw. For an accurate reading, ensure that the screw flange is flush against the shelf marked "Screw Diameter". (Figure 11)

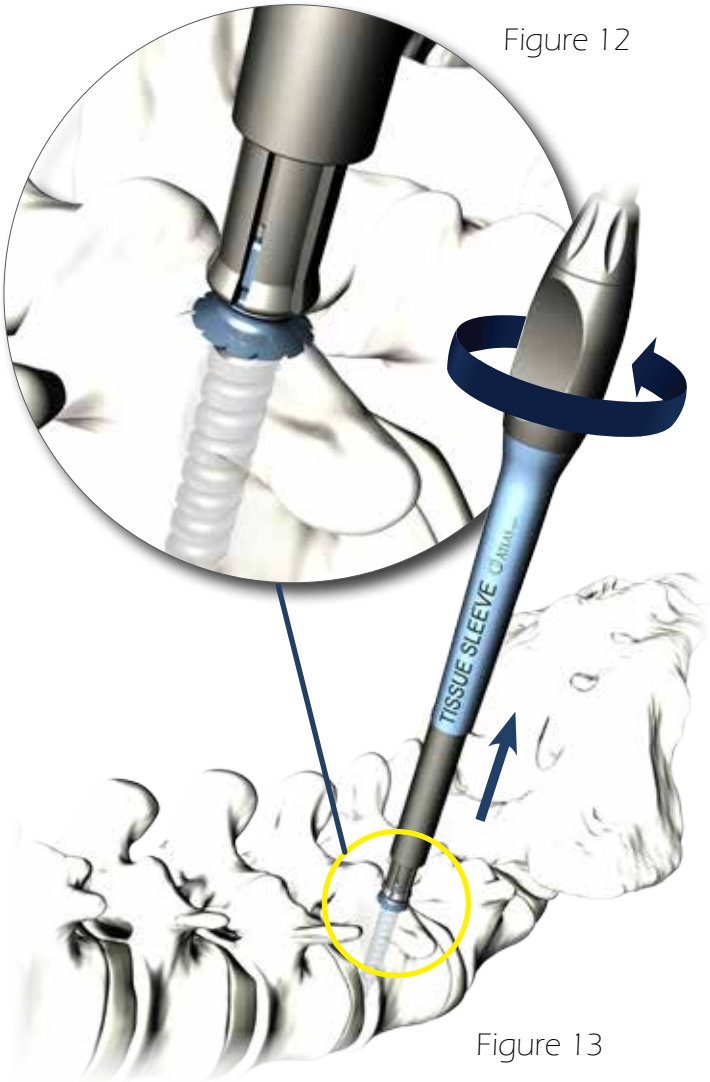


Figure 12

- SCREW INSERTION:

As the screw is advanced by turning the driver handle clockwise, the Modular Screwdriver can be steadied by holding the blue Tissue Sleeve.

*Note: To avoid inadvertent disassembly of the Modular Screwdriver/Screw do not hold the thumb grip during screw insertion.

*Note: When inserting the screw, the screw should be advanced to, but not past, the flange. Attempting to advance the screw past the flange will result in excessive force on the screwdriver and pedicle.

Figure 13

- DISENGAGING THE SCREWDRIVER:

. After the screw is fully inserted, the Modular Screwdriver will be removed by fully rotating the thumb grip counter clockwise while immobilizing the Modular Screwdriver handle and then gently lifting the Modular Screwdriver off the screw. (Figure 12 and 13)

STEP 4: HEAD ATTACHMENT

- HEAD GROOMING:

The Head Grooming Tool may be used prior to head application in order to clear any bony structures that may interfere with head application or restrict polyaxial movement. (Figure 14)

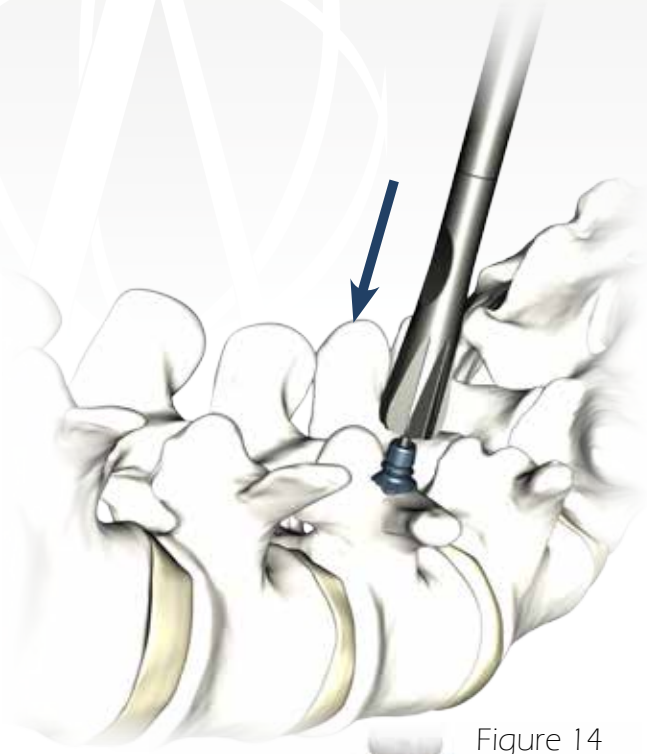


Figure 14

- STANDARD HEAD APPLICATION:

If a standard or reduction head is selected, the Threaded Head Applicator will be used to pick the head out of the caddy by dropping the plunger down the center of the tulip and rotate the knob clockwise to engage the threads on the head until the instrument bottoms. (Figure 15)

Proper loading of the head on the Threaded Head Applicator can be verified by cofirming that the plunger of the Threaded Head Applicator extends past the bottom of the head and that the teeth of the collet are visible. (Figure 16)

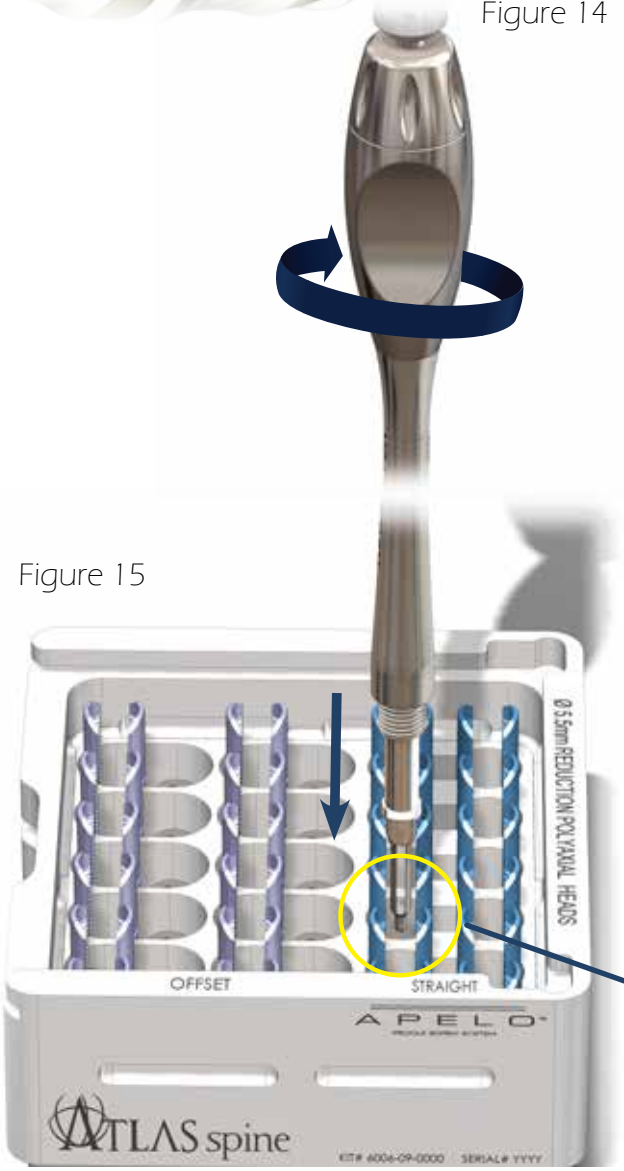


Figure 15

Figure 16

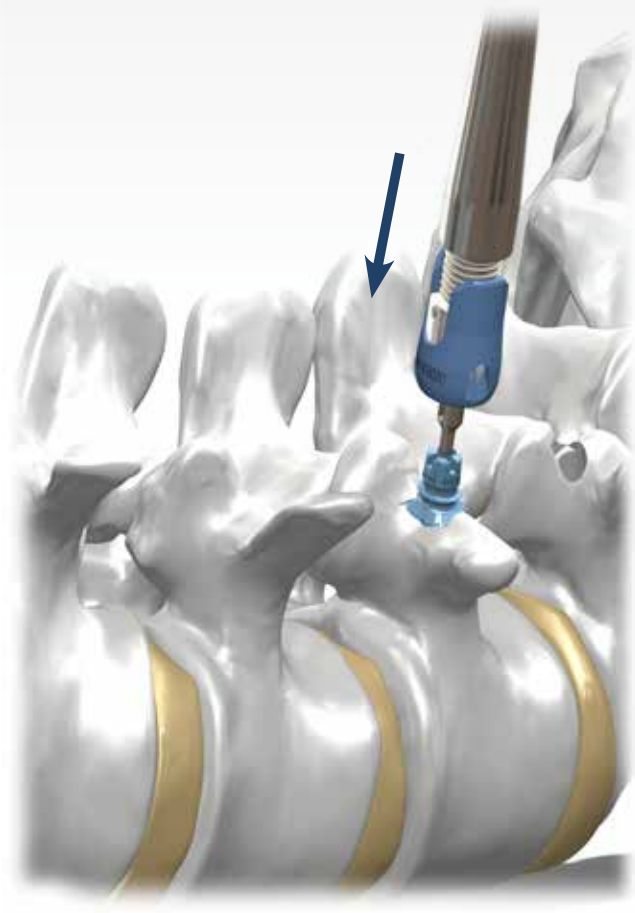


Figure 17

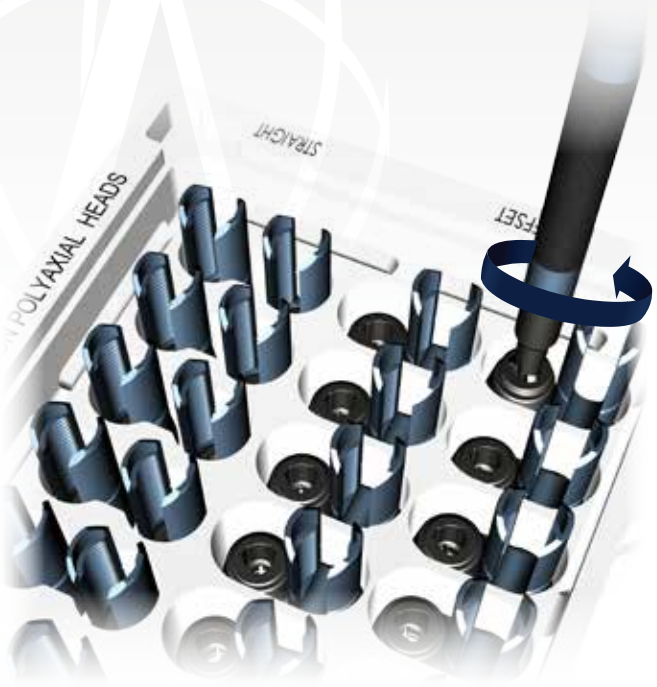
To apply the head to the screw, align the Threaded Head Applicator with the trajectory of the screw, insert the plunger into the center of the screw's head, and press deliberately until a click is heard and felt. (Figure 17)

*Note: It is recommended that reduction heads be used at all times to ease the placement of rods and Locking Collars.

Figure 18

- CONFIRMATION OF HEAD ATTACHMENT: After a head is applied to a screw, firmly tug on the head to ensure proper connection. To remove the instrument rotate the knob counterclockwise till the instrument releases form the head. (Figure 18)

*Note: If difficulty is encountered when applying the head, use the head Grooming Tool to remove any potential interference.



- OFFSET HEAD APPLICATION:

If an Offset Head is selected, the Head Applicator will be used to pick the head out of the caddy by dropping the plunger through the offset portion of the head.

*Note: ensure that the set screw in the offset portion of the head is fully rotated counter-clockwise using the Dual Locking Collar Starter before inserting the Head Applicator. If the set screw is not rotated counter-clockwise, the head will not attach to the screw. (Figure 19)

Figure 19

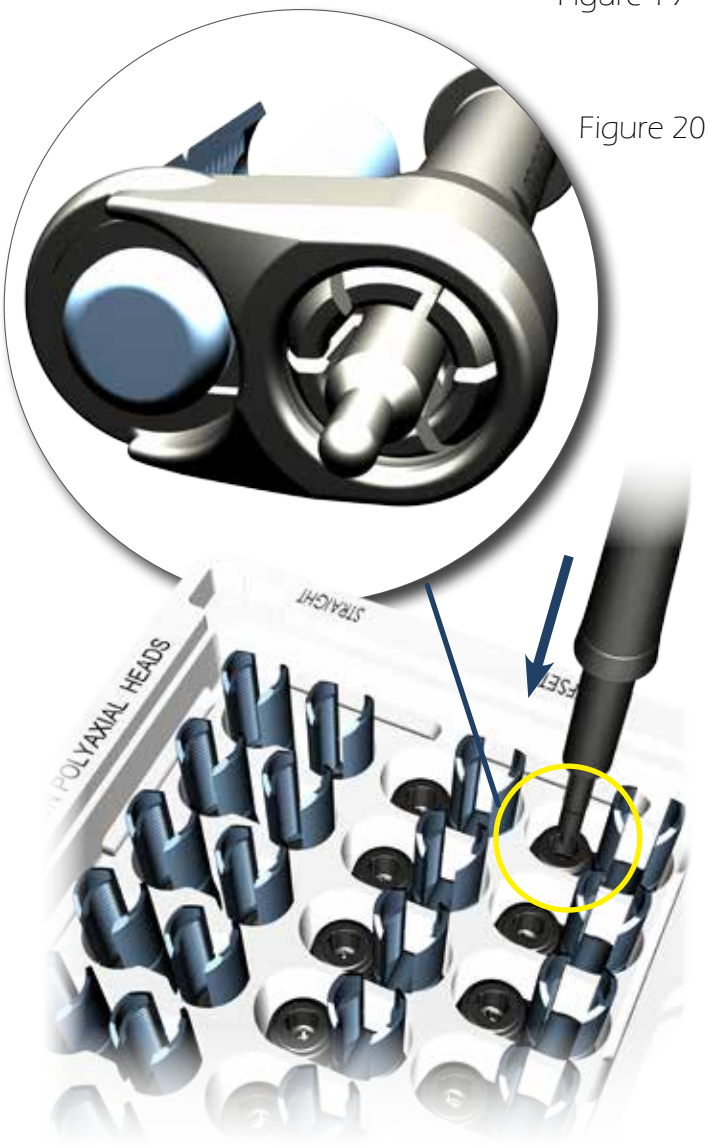


Figure 20

Proper loading of the head on the Head Applicator can be verified by confirming that the plunger of the Head Applicator extends past the bottom of the head and that the teeth of the collet are visible. (Figure 20)

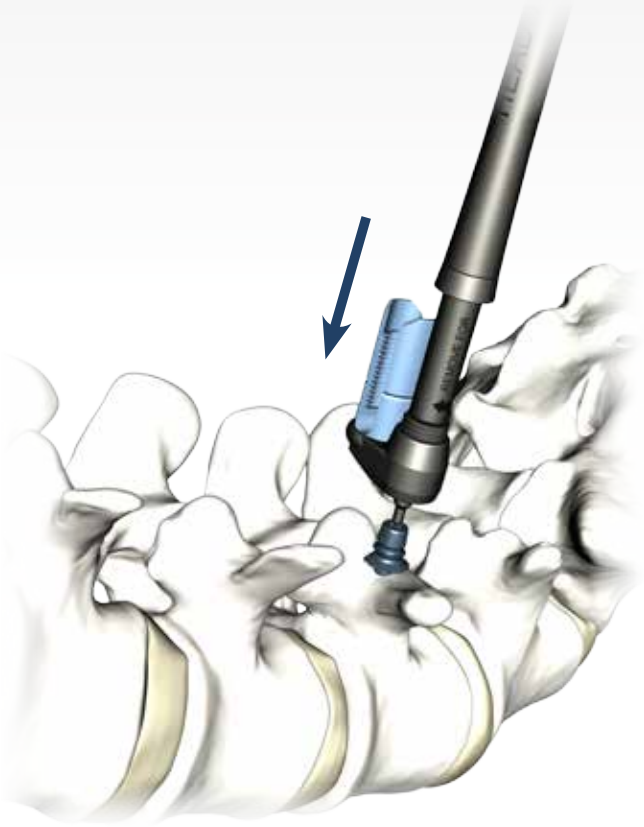


Figure 21

To apply the head to the screw, align the Head Applicator with the trajectory of the screw, insert the plunger into the center of the screw's head, and press until a click is heard and felt. (Figure 21)

- CONFIRMATION OF ATTACHMENT:

After a head is applied to a screw, firmly tug on the head to ensure proper connection. This should be done prior to rod placement (refer to Figure 18).

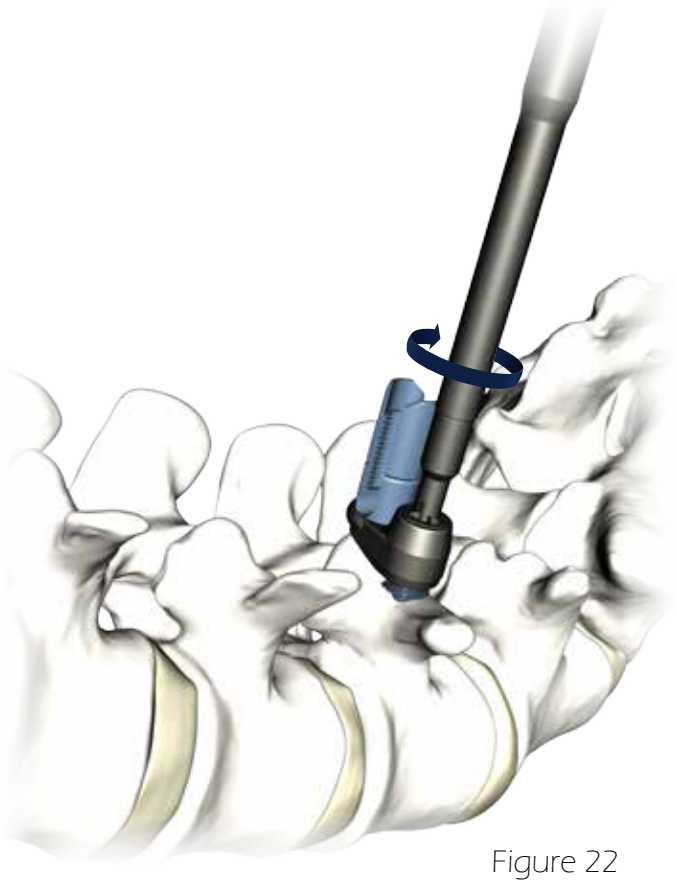


Figure 22

Unlike the standard head, the polyaxial capability of the Offset Head is not eliminated when the rod is placed and the Locking Collars are fully tightened. The surgeon must tighten the set screw clockwise using the Torque Driver in order to restrict polyaxial movement. This can be done at the surgeon's discretion at any point after the head is applied to the screw. (Figure 22)

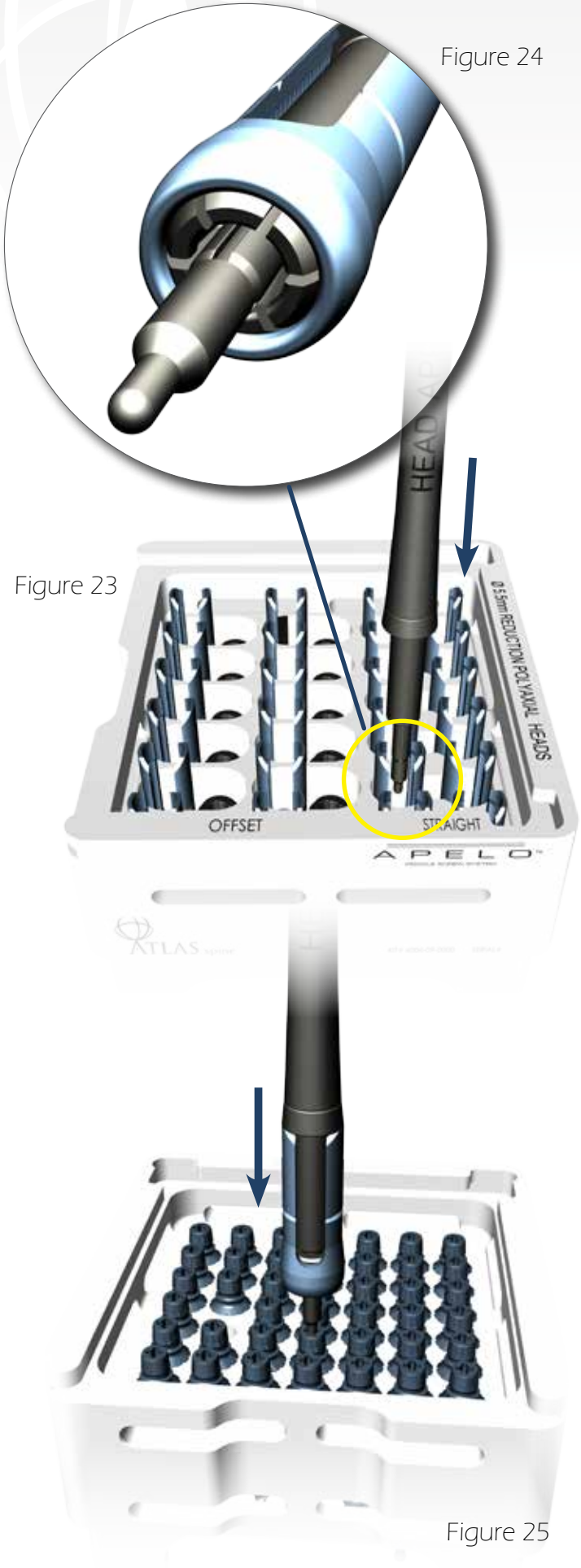


Figure 24

Figure 23

POLYAXIAL SCREW INSERTION

If desired, the Apelo head can be applied to the screw outside the wound and inserted as an assembled polyaxial screw.

To apply the head to the screw, align the Head Applicator with the trajectory of the screw, which should be sitting vertically inside the screw caddy. Next, insert the plunger into the center of the screw's head and press until a click is heard and felt. (Figure 25).

- CONFIRMATION OF HEAD ATTACHMENT:

After a head is applied to a screw, firmly tug on the head to ensure proper connection. This should be done prior to attaching the poly driver.

Figure 25

Figure 26

- POLY DRIVER ASSEMBLY:

The blue Tissue Sleeve should be inserted onto the Poly Driver until it is flush with the thumb grip before any screw is loaded. (Figure 26)

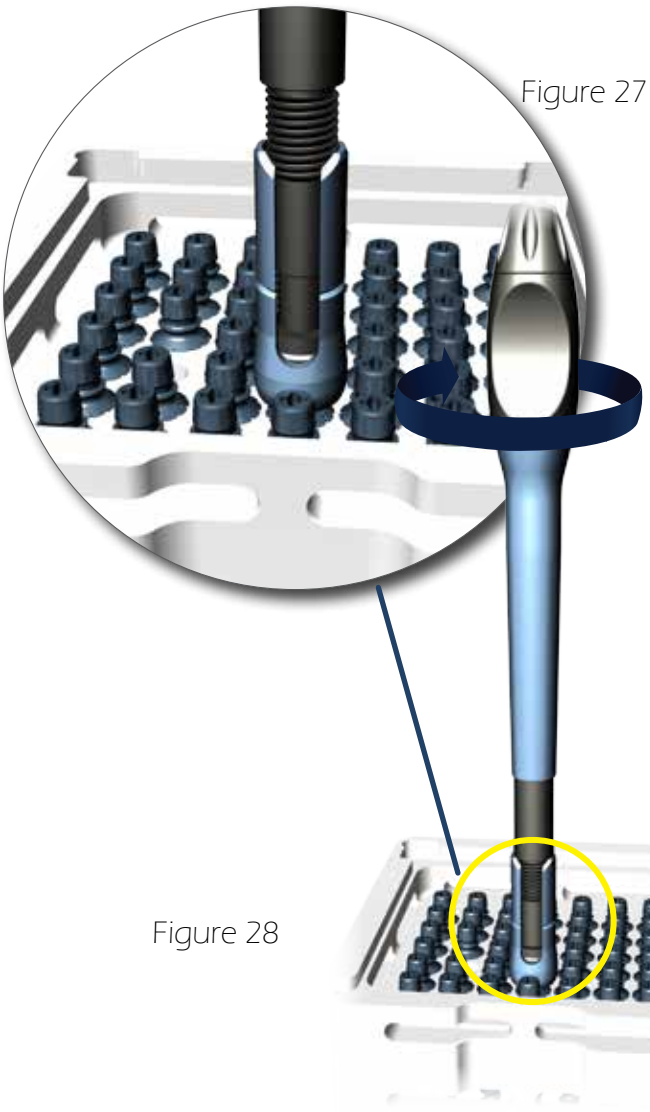


Figure 27

- POLY DRIVER TO HEAD/SCREW INTERFACE:

Once the head is loaded to the screw, the Poly Driver should be attached to the screw/head. Align the Poly Driver with the center of the head and rotate until the driver drops fully into the screw. A proper connection between the screw and driver can be verified by confirming that the cross-member is fully seated in the tulip saddle. (Figure 27)

Figure 28

The thumb grip should then be fully rotated clockwise to secure the screw/head construct to the Poly Driver. (Figure 28)

*Note: Be sure to use the Poly Driver that coordinates with each head style. The drivers are marked "Reduction" and "Non-Reduction" on the shaft.

Figure 29

- VERIFYING SCREW SIZE:

The Screw Sizing Template may be used to verify both the diameter and length of the screw. For an accurate reading, ensure that the screw flange is flush against the shelf marked "Screw Diameter". (Figure 29)

- SCREW INSERTION:

*Note: When inserting the screw, the screw should be advanced to, but not past, the flange. Attempting to advance the screw past the flange will result in excessive force on the screwdriver and pedicle.

Figure 30

- DISENGAGING THE SCREW DRIVER:

After the screw is fully inserted, the Poly Driver will be removed by rotating the thumb grip counter clockwise while immobilizing the Poly Driver handle. (Figure 30)

STEP 5: SCREW HEIGHT ADJUSTMENT AND HEAD REMOVAL

Figure 31

- SCREW HEIGHT ADJUSTMENT:

If irregular anatomy presents a problem with screw height or the screw is not fully seated, the Adjustment Driver may be used before or after the head is attached to engage the screw and adjust the height of the screw. (Figure 31)

Figure 32

- HEAD REMOVAL:

If there is a need to change or remove the head from the screw, the Head Removal Tool may be used to remove the head without causing it damage. To effectively use the Head Removal Tool, align the tool with the screw trajectory and thread the tip into the collet in the head until the head slides off.

***Note: Applying upward or downward force on the head will help the Head Removal Tool engage the head and make removal easier.** (Figure 32)

STEP 6: ROD AND LOCKING COLLAR APPLICATION (OPTIONAL: COMPRESSION AND DISTRACTION)

Figure 33

- ROD SELECTION:

Prior to applying a rod, a flexible Rod Template marked in 10mm increments is available to approximate what size rod will be used.

- ROD CONTOURING:

A French Rod Bender for further contouring of rods is available. (Figure 33)

*Note: Do not overcycle.

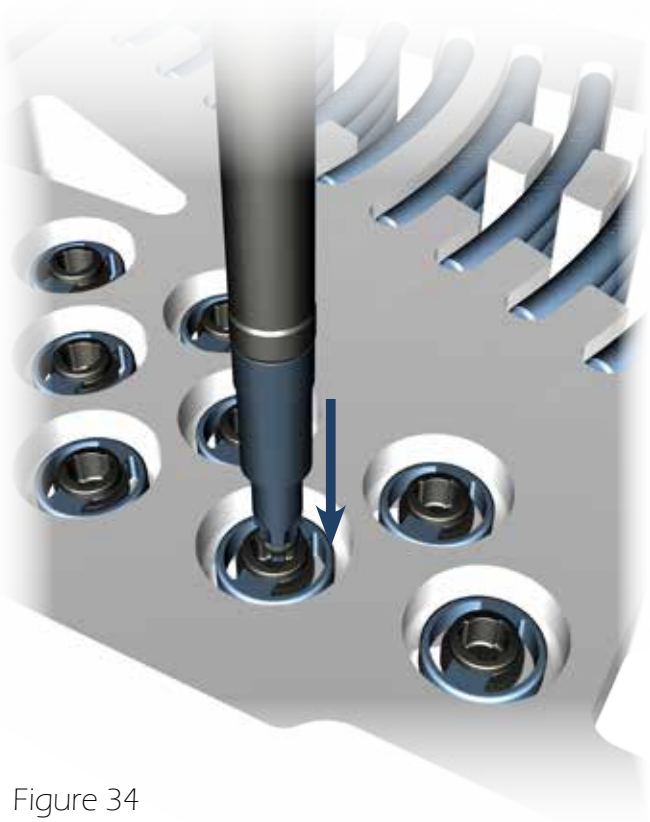


Figure 34

- LOCKING COLLAR SELECTION:

The Dual Locking Collar Starter should be used for removing the Locking Collars from the caddy and initial application to the head. Locking Collars may be loaded at both ends of the Dual Locking Collar Starter for expediency. (Figure 34)

Figure 35

*Note: The Standard Locking Collars are for use only on the Standard and Standard Reduction Heads. Offset Locking Collars must be used on offset head options. (Figure 35)

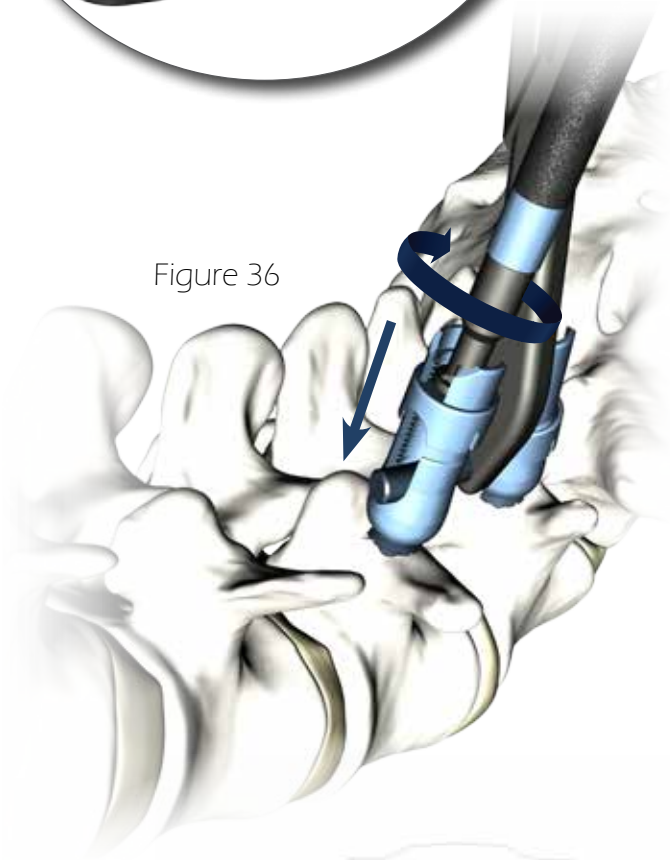


Figure 36

- ROD AND LOCKING COLLAR ASSEMBLY:

Once a rod size is selected, the Curved Rod Holder may be used to remove the rod from the caddy and place it in the tulip heads. The rod holder should remain holding the rod until the Locking Collars are provisionally tightened. (Figure 36)

Figure 37

- ROD APPROXIMATOR:

Reduction heads provide 25 mm of threaded reduction built into the head. If standard non-reduction heads are used, a Rod Approximator may be used for rod reduction. Prior to attaching the Rod Approximator to the head, load the Approximator Guide by assembling into the j-slot as shown. The Approximator Guide aides in correctly attaching the Approximator to the head. (Figure 37)

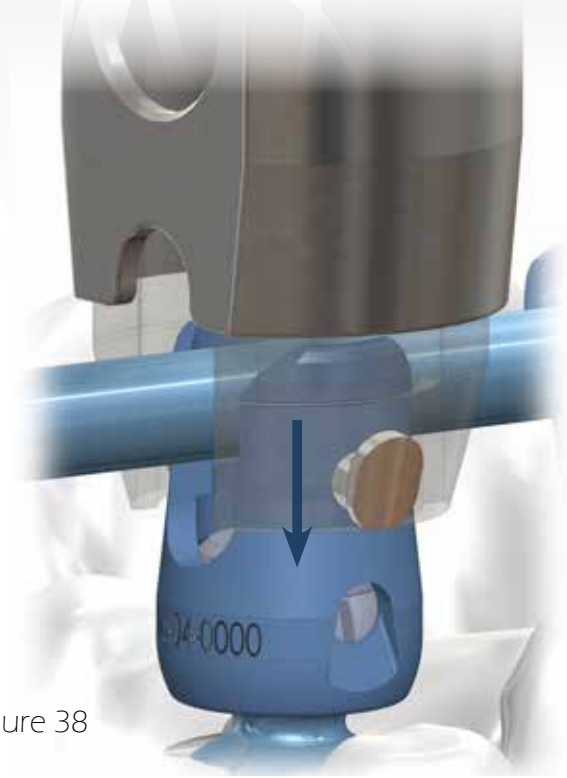


Figure 38

Apply the Rod Approximator to the head by pressing down in line with the head until the pins on the approximator engage the slots on the head. Tug to ensure adequate connection. Note that the handle must remain open when attaching the Rod Approximator to the head. (Figure 38)

Figure 39

Squeeze the handle to reduce the rod into the head. A laser marking on the Rod Approximator will become visible once the rod is fully seated into the head. The Locking Collar will not engage if the laser mark line is not visible. Remove the Approximator Guide from the Rod Approximator. (Figure 39)

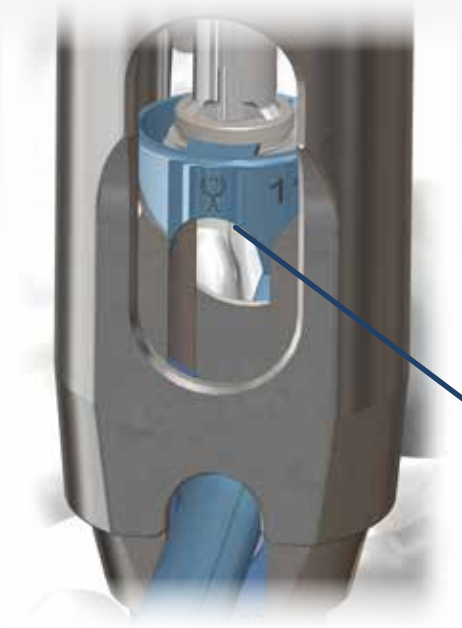


Figure 40

Insert a Standard Locking collar down the Rod Approximator. Align the rod slot on the collar with the rod prior to insertion into the Rod Approximator. A window on the Rod Approximator allows visualization if the Rod Slot remains aligned with the rod. (Figure 40)

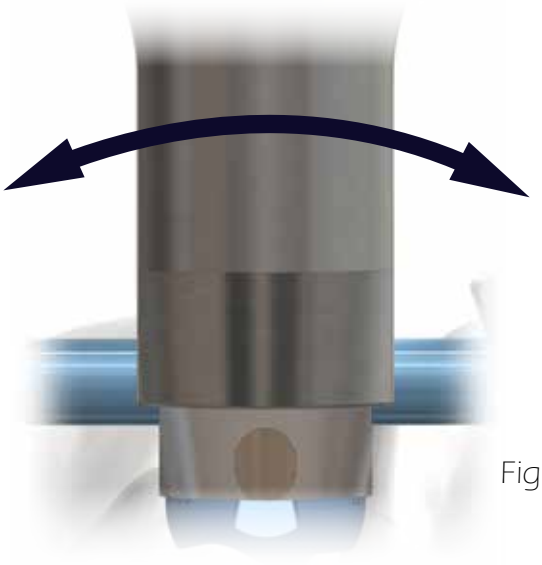


Figure 41

Release the handle ratchet and allow the instrument to open fully. Rock the instrument cephalad/caudal to remove the Rod Approximator from the head. (Figure 41)

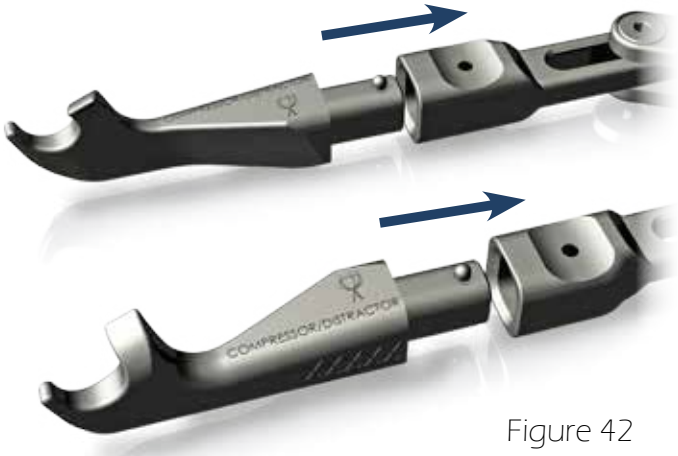


Figure 42

- COMPRESSION/DISTRACTION ASSEMBLY:

Select the appropriate Compressor/Distractor Tips and insert them into the Compressor/Distractor until they click firmly into place.

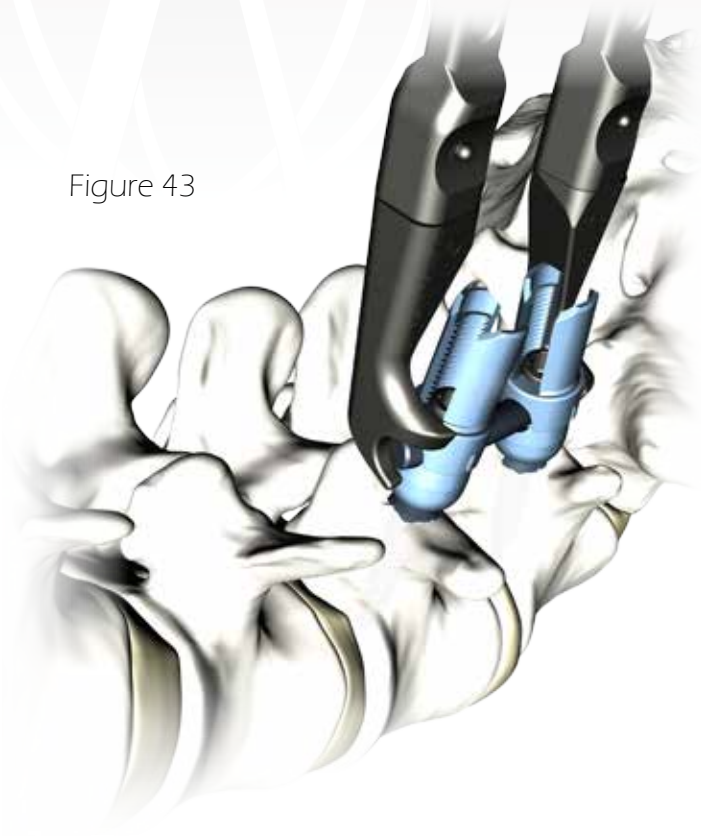


Figure 43

- COMPRESSION/DISTRACTION APPLICATION:
Properly orient and position the Compressor/Distractor over the rod and heads. Squeeze the handle until desired compression/distraction is achieved.

Figure 44

- FINAL TIGHTENING:
Final tightening of the Locking Collars should be performed using the Torque Driver, Torque Limiting T-handle, and Counter-Torque. (Figure 44)

*Note: Do not use the Locking Collar Starter for final tightening of the Locking Collars as this could cause damage to the Dual Locking Collar Starter.

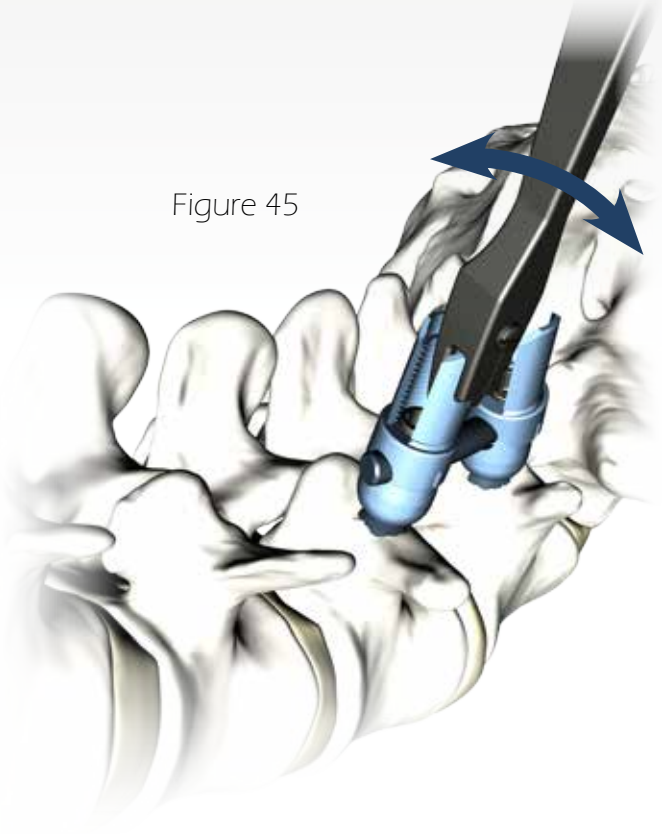


Figure 45

- TAB REMOVAL:

For both styles of reduction heads, the Tab Removal Tool should be used to remove the extended tabs. The long arm of the Tab Removal Tool should be inserted on the inside of the head tulips and then rocked back and forth to break the tabs. Failure to do so could result in difficulty removing the tabs. Do not pull up while breaking the tab or it may not stay retained in the instrument. If using the Tab Breaker, the button may be depressed once broken to release the tab from the instrument. (Figure 45)

***Note: Final tightening must be done prior to breaking tabs. Failure to do so could result in difficulty removing the reduction tabs.**

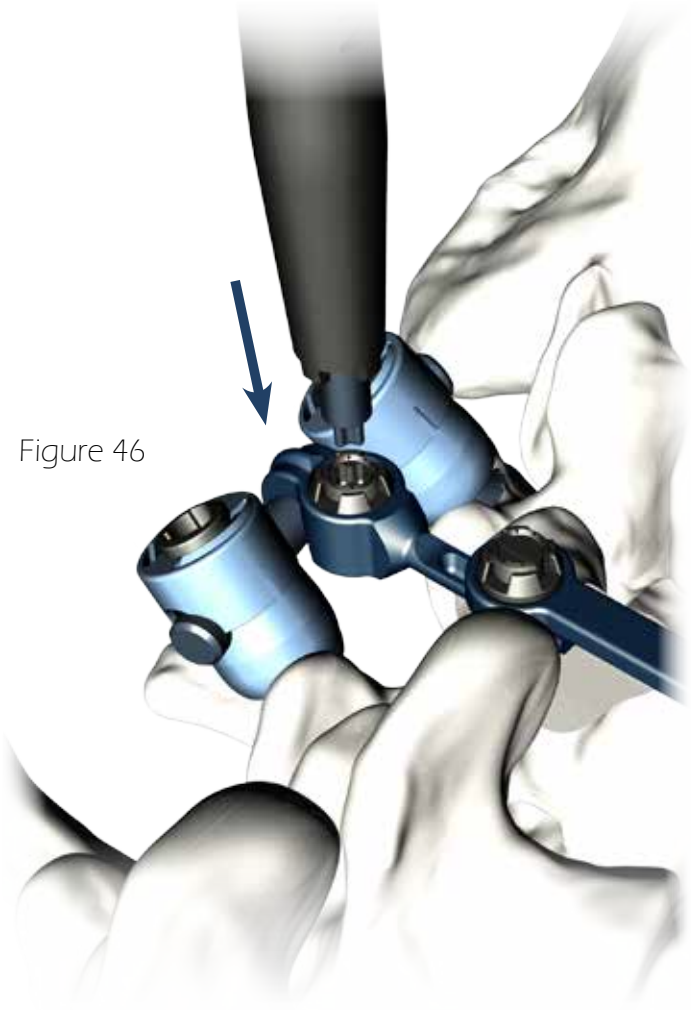


Figure 46

STEP 7: CROSS CONNECTOR APPLICATION

- CROSS CONNECTOR ATTACHMENT:

The DLC crosslink is designed with adjustability to accommodate the majority of clinical situations encountered.

Once the appropriate size has been selected, attach the crosslink by placing the claw onto each rod. (Figure 46) The cam mechanism is secured to the rod by using the Cam Driver and Nut Driver in combination.

Note: The cam mechanism is stored preset in the open (ready) position and should not be adjusted prior to attachment.

Figure 47

- CROSS CONNECTOR LOCKING:

To lock; engage the Cam Driver into the clover drive of the cam and rotate up to 180° **counter clockwise** (left) until firm. Once the cam has been secured, engage the Nut Driver into the slots of the Locking Nut and rotate **clockwise** (right) until firm. (Figure 47) The locking nut will prohibit the cam from counter rotation.

*Note: When locking the crosslinks, rotate the Cam and Nut Driver in the direction indicated on each shaft. The Cam Driver does not have a torque limiting feature and should not be rotated past the arc indicated on the driver.

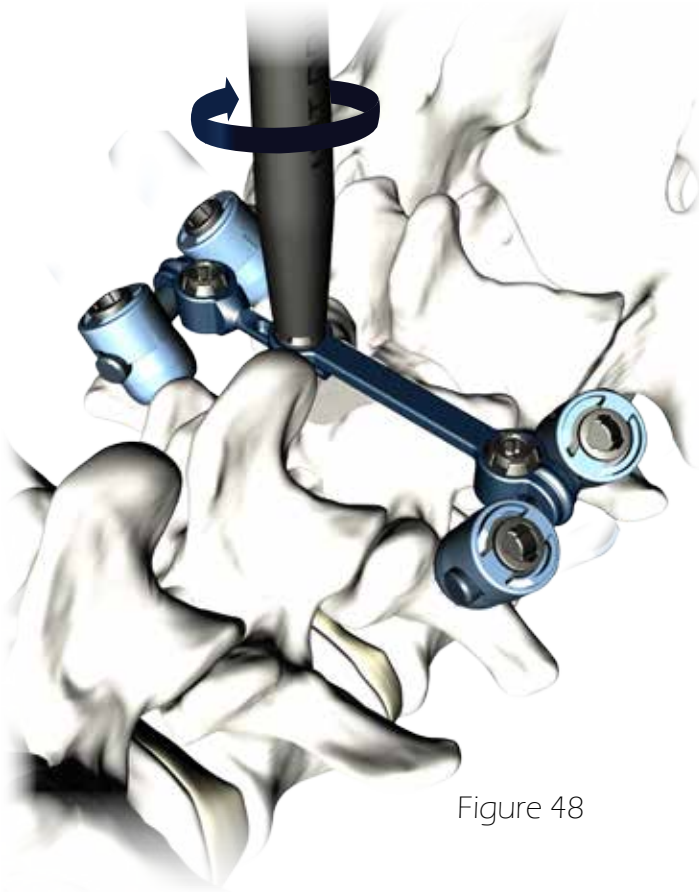
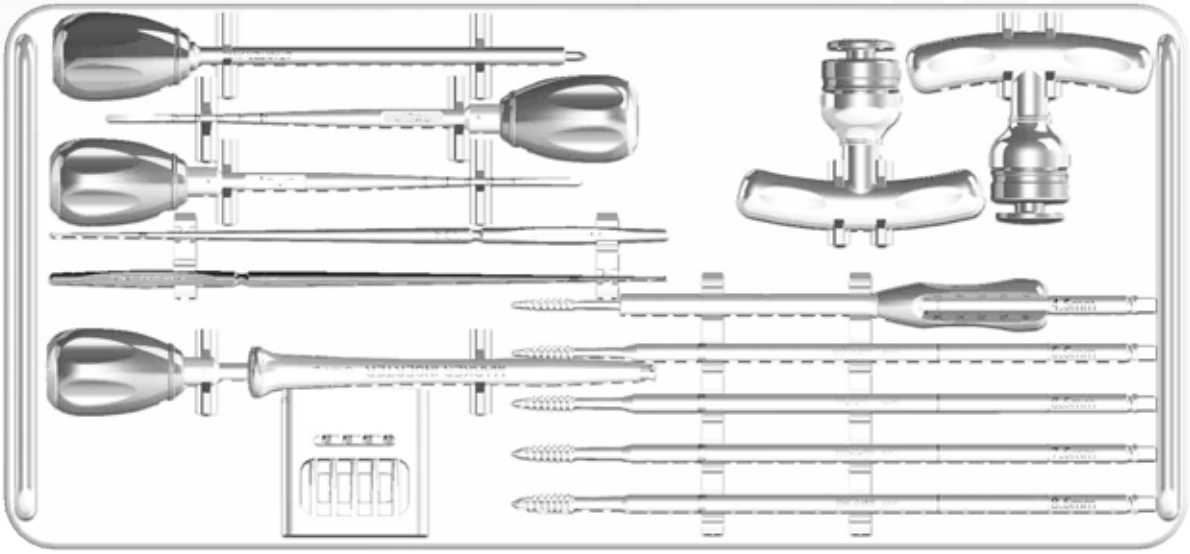


Figure 48

The central adjustment locking nut can be locked once the crosslink has been secured to the rod. To lock engage the Nut Driver into the slots of the Central Locking nut and rotate clockwise until firm. (Figure 48)

TRAY LAYOUT
INSTRUMENT SET 1

Top



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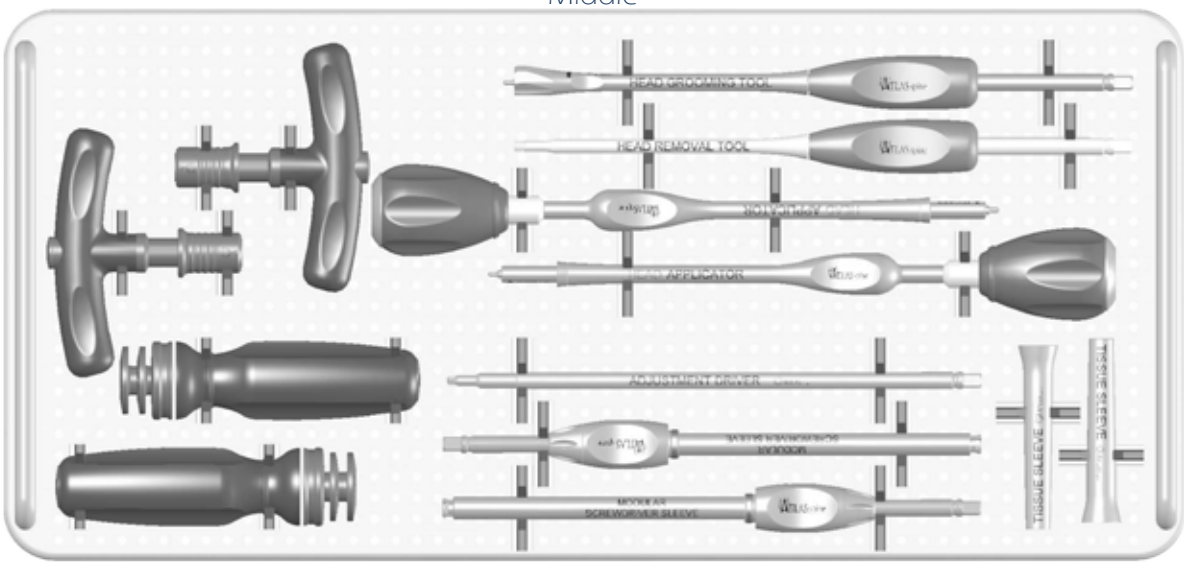

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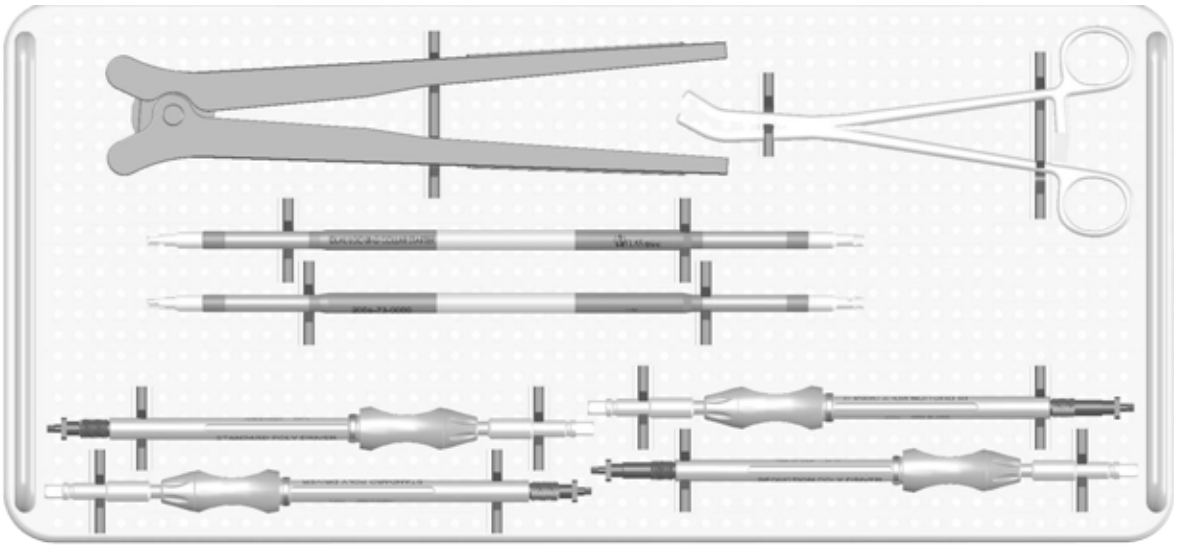
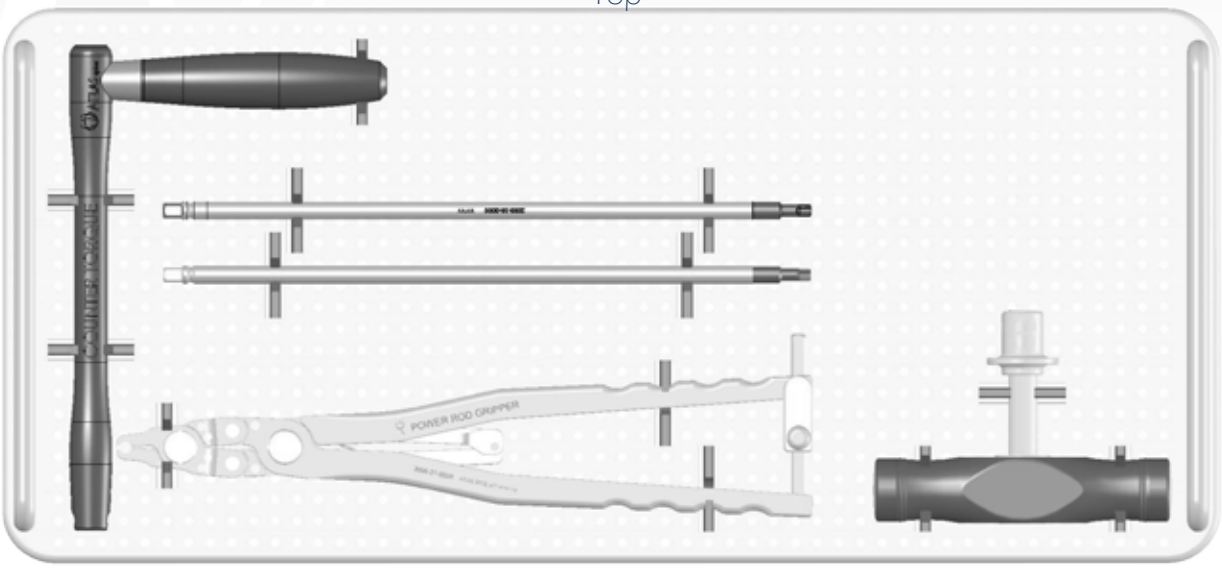


TRAY LAYOUT
INSTRUMENT SET 2

Top



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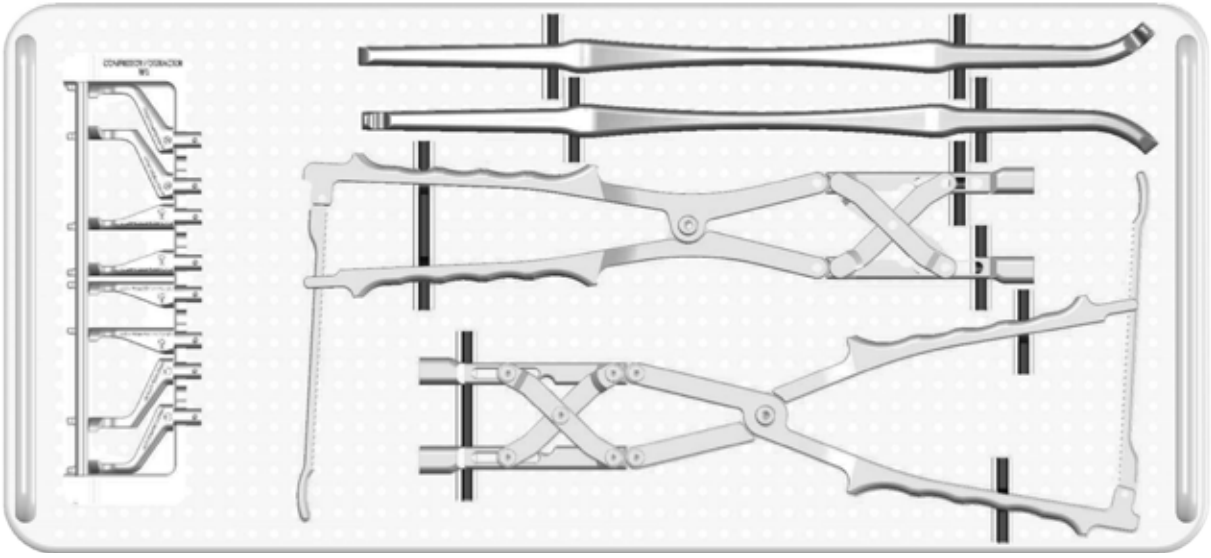

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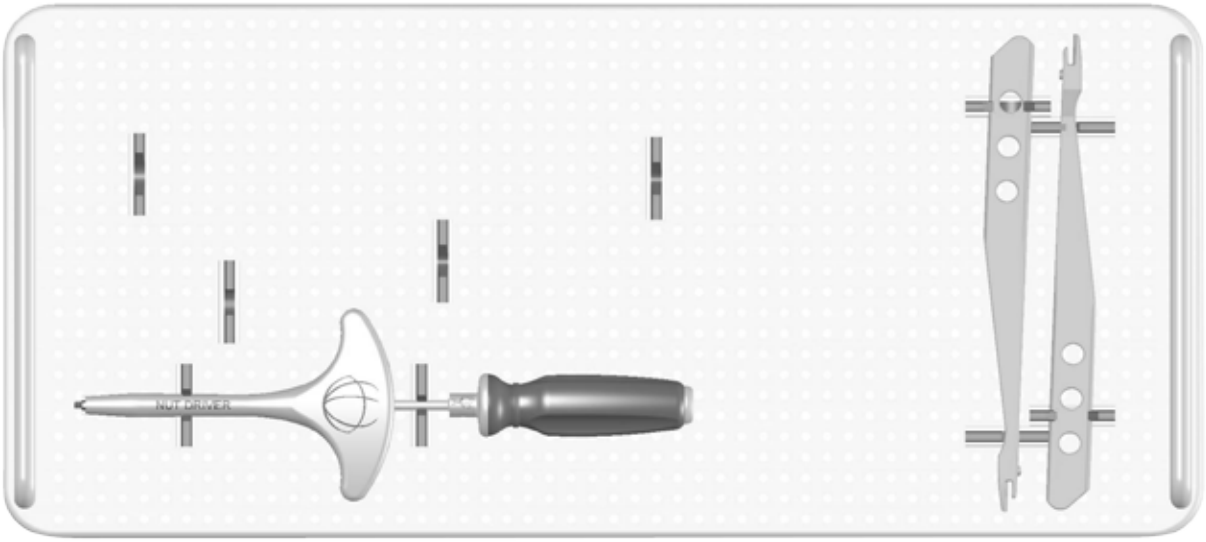

CATALOG NUMBERS

INSTRUMENTS

INSTRUMENT SET 1

2006-04-0000	Head Alignment Tool
2006-05-0000	Head Applicator
2006-06-0000	Head Grooming Tool
2006-07-0000	Head Removal Tool
2006-12-0000	Marker Inserter Sleeve
2006-13-0425	4.5mm Bone Tap
2006-13-0525	5.5mm Bone Tap
2006-13-0625	6.5mm Bone Tap
2006-13-0725	7.5mm Bone Tap
2006-13-0825	8.5mm Bone Tap
2006-14-0000	Bone Tap Sleeve
2006-15-0000	Starter Awl
2006-17-0000	French Rod Bender
2006-18-0000	Ratcheting In-Line Handle
2006-30-0000	Curved Sounding Probe
2006-31-0000	Straight Sounding Probe
2006-33-0000	T-Handle
2006-34-0000	Ratcheting T-Handle
2006-36-0000	Left X-Ray Marker
2006-37-0000	Right X-Ray Marker
2006-39-0000	Tissue Sleeve
2006-40-0000	Modular Screwdriver Sleeve
2006-41-0000	Modular Screwdriver Shaft
2006-42-0000	Locking Collar Starter
2006-51-0000	Curved Rod Holder
2006-53-0000	Adjustment Driver
2006-59-0000	Curved Pedicle Probe
2006-60-0000	Straight Pedicle Probe
4000-07-0000	X-Ray Marker Caddy

INSTRUMENT SET 2

2006-01-0000	Counter Torque
2006-03-0000	Cross Connector Sizing Template
2006-16-0000	Distractor
2006-21-0000	Compressor/Distractor Tip -001
2006-22-0000	Compressor/Distractor Tip -002
2006-25-0000	Compressor
2006-27-0000	Power Rod Gripper
2006-32-0000	Tab Removal Tool
2006-35-0000	Torque Limiter T-Handle
2006-38-0000	Torque Driver
2006-52-0000	Right Offset Compressor Tip
2006-54-0000	Left Offset Compressor Tip
2006-55-0000	Right Offset Distractor Tip
2006-56-0000	Left Offset Distractor Tip
2006-57-0000	Right In-Situ Bender
2006-58-0000	Left In-Situ Bender
2006-11-0000	Nut Driver
2006-47-0000	Cam Driver
4006-20-0000	Compressor/Distractor Modular Tip Caddy

ADDITIONAL INSTRUMENTS AVAILABLE

2106-63-0000	Standard Mono Driver
2106-64-0000	Reduction Mono Driver

IMPLANT SET

5.5 mm MODULAR SCREWS

1106-01-5525	5.5mm x 25mm Modular Screw
1106-01-5530	5.5mm x 30mm Modular Screw
1106-01-5535	5.5mm x 35mm Modular Screw
1106-01-5540	5.5mm x 40mm Modular Screw
1106-01-5545	5.5mm x 45mm Modular Screw

6.5 mm MODULAR SCREWS

1106-01-6525	6.5mm x 25mm Modular Screw
1106-01-6530	6.5mm x 30mm Modular Screw
1106-01-6535	6.5mm x 35mm Modular Screw
1106-01-6540	6.5mm x 40mm Modular Screw
1106-01-6545	6.5mm x 45mm Modular Screw
1106-01-6550	6.5mm x 50mm Modular Screw
1106-01-6555	6.5mm x 55mm Modular Screw
1106-01-6560	6.5mm x 60mm Modular Screw

7.5 mm MODULAR SCREWS

1106-01-7530	7.5mm x 30mm Modular Screw
1106-01-7535	7.5mm x 35mm Modular Screw
1106-01-7540	7.5mm x 40mm Modular Screw
1106-01-7545	7.5mm x 45mm Modular Screw
1106-01-7550	7.5mm x 50mm Modular Screw
1106-01-7555	7.5mm x 55mm Modular Screw
1106-01-7560	7.5mm x 60mm Modular Screw

8.5 mm MODULAR SCREWS

1106-01-8530	8.5mm x 30mm Modular Screw
1106-01-8535	8.5mm x 35mm Modular Screw
1106-01-8540	8.5mm x 40mm Modular Screw
1106-01-8545	8.5mm x 45mm Modular Screw
1106-01-8550	8.5mm x 50mm Modular Screw
1106-01-8555	8.5mm x 55mm Modular Screw
1106-01-8560	8.5mm x 60mm Modular Screw

5.5 mm STRAIGHT RODS

1100-01-0030	5.5mm x 30mm Straight Rod
1100-01-0035	5.5mm x 35mm Straight Rod
1100-01-0040	5.5mm x 40mm Straight Rod
1100-01-0045	5.5mm x 45mm Straight Rod
1100-01-0050	5.5mm x 50mm Straight Rod
1100-01-0055	5.5mm x 55mm Straight Rod
1100-01-0060	5.5mm x 60mm Straight Rod
1100-01-0065	5.5mm x 65mm Straight Rod
1100-01-0070	5.5mm x 70mm Straight Rod
1100-01-0075	5.5mm x 75 mm Straight Rod

1100-01-0080	5.5mm x 80mm Straight Rod
1100-01-0085	5.5mm x 85mm Straight Rod
1100-01-0090	5.5mm x 90mm Straight Rod
1100-01-0095	5.5mm x 95mm Straight Rod
1100-01-0100	5.5mm x 100mm Straight Rod
1100-01-0105	5.5mm x 105mm Straight Rod
1100-01-0110	5.5mm x 110mm Straight Rod
1100-01-0200	5.5mm x 200mm Straight Rod
1100-01-0300	5.5mm x 300mm Straight Rod
1100-01-0400	5.5mm x 400mm Straight Rod
1100-01-0500	5.5mm x 500mm Straight Rod

5.5 mm CONTOURED RODS

1100-03-0030	5.5mm x 30mm Contoured Rod
1100-03-0035	5.5mm x 35mm Contoured Rod
1100-03-0040	5.5mm x 40mm Contoured Rod
1100-03-0045	5.5mm x 45mm Contoured Rod
1100-03-0050	5.5mm x 50mm Contoured Rod
1100-03-0055	5.5mm x 55mm Contoured Rod
1100-03-0060	5.5mm x 60mm Contoured Rod
1100-03-0065	5.5mm x 65mm Contoured Rod
1100-03-0070	5.5mm x 70mm Contoured Rod
1100-03-0075	5.5mm x 75mm Contoured Rod
1100-03-0080	5.5mm x 80mm Contoured Rod
1100-03-0085	5.5mm x 85mm Contoured Rod
1100-03-0090	5.5mm x 90mm Contoured Rod
1100-03-0095	5.5mm x 95mm Contoured Rod
1100-03-0100	5.5mm x 100mm Contoured Rod
1100-03-0105	5.5mm x 105mm Contoured Rod
1100-03-0110	5.5mm x 110mm Contoured Rod

HEADS

1106-04-0000	Standard Head
1106-05-0000	Standard Reduction Head
1106-06-0000	Offset Head
1106-07-0000	Offset Reduction Head

LOCKING COLLAR

1106-08-0000	Offset Locking Collar
1106-09-0000	Standard Locking Collar

CROSS CONNECTOR

1100-05-4248	42-48mm Variable Cross Connector
1100-05-4854	48-54mm Variable Cross Connector
1100-05-5460	54-60mm Variable Cross Connector
1100-05-6066	60-66mm Variable Cross Connector
1100-05-6672	66-72mm Variable Cross Connector

ADDITIONAL IMPLANTS AVAILABLE

4.5 mm MODULAR SCREWS

4.5mm x 25mm to 4.5mm x 45mm Modular Screw

MONO SCREWS

4.5 mm MONO SCREWS

4.5mm x 25mm to 4.5mm x 45mm Mono Screw

5.5 mm MONO SCREWS

5.5mm x 25mm to 5.5mm x 45mm Mono Screw

6.5 mm MONO SCREWS

6.5mm x 25mm to 6.5mm x 60mm Mono Screw

7.5 mm MONO SCREWS

7.5mm x 30mm to 7.5mm x 60mm Mono Screw

8.5 mm MONO SCREWS

8.5mm x 30mm to 8.5mm x 60mm Mono Screw

REDUCTION MONO SCREWS

4.5 mm REDUCTION MONO SCREWS

4.5mm x 25mm to 4.5mm x 45mm Reduction Mono Screw

5.5 mm REDUCTION MONO SCREWS

5.5mm x 25mm to 5.5mm x 45mm Reduction Mono Screw

6.5 mm REDUCTION MONO SCREWS

6.5mm x 25mm to 6.5mm x 60mm Reduction Mono Screw

7.5 mm REDUCTION MONO SCREWS

7.5mm x 30mm to 7.5mm x 60mm Reduction Mono Screw

8.5 mm REDUCTION MONO SCREWS

8.5mm x 30mm to 8.5mm x 60mm Reduction Mono Screw

FIXED CROSS CONNECTOR

20 mm to 42 mm Fixed Cross Connector in increments of 2

INSTRUCTIONS FOR USE

Single Use Only - Must be sterilized prior to use.

Description:
The **Apelo™ Pedicle Screw System** is a system which contains of an assortment of monoaxial and polyaxial screws, adjustable cross connectors, rods, offset and straight receptacle bases with and without reduction tabs, and collar assemblies.

Indications:
The **Apelo™ Pedicle Screw System** is intended for noncervical pedicle fixation in skeletally mature patients as an adjunct to fusion for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis; trauma (i.e., fracture or dislocation); spinal stenosis; curvatures (i.e., scoliosis, kyphosis, and/or lordosis); tumor; pseudarthrosis; and failed previous fusion.

Material:
The **Apelo™ Pedicle Screw System** is manufactured from implantable titanium alloy (Ti6Al4V ELI) per ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).

Cleaning and Sterilization:
The **Apelo™ Pedicle Screw System** is supplied clean and non-sterile and is intended to be sterilized prior to use. Each device may be supplied individually in bags or in a preformed tray and is intended to be sterilized prior to use. Sterilize following AAMI standards and a validated cycle to achieve a sterility assurance level (SAL) of 10-6 or better. Atlas Spine recommends wrapped, pre-vacuum steam sterile at 270oF for a minimum of 4 minutes. Following sterilization, implants should be dried and/or cooled to prevent condensation.

Cycle Type	Pre-Vacuum
Cycle Time	4 minutes
Temperature	270° F
Dry Time	30 minutes

Only sterile products should be used in the operative field.

General Conditions of Use:
The physician must be thoroughly knowledgeable not only in the medical and surgical aspects of the implants but must also be aware of the mechanical and material limitations of metallic surgical implants. Appropriate postoperative care is extremely important for achieving successful results.

⚠ Prior to use refer to the **Apelo™ Pedicle Screw System Surgical Technique Guide** for surgical procedure information and surgical instrument reprocessing recommendations. **Apelo™ Pedicle Screw System Surgical Technique Guide** is available by contacting Atlas Spine by telephone **561-741-1108** or by email at **Orders@AtlasSpine.com**

Patient Selection:
When considering prospective surgical candidates, the following factors can significantly influence the eventual outcome and success of the procedure:

1. Occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until complete fusion has been attained. Even when fully recovered, the patient may not be able to return to these activities successfully.

2. Diminished mental capacity. Conditions such as senility, mental illness, alcoholism, and drug abuse, can contribute to noncompliance with prescribed limitations and precautions and thereby impede or prevent postoperative rehabilitation.

3. Degenerative disease. Progressive musculoskeletal, metabolic, or neurologic degenerative disease may be so advanced as to prevent satisfactory implantation, impair stabilization, and/or limit the useful life of the implant and surgery should only be undertaken as a shortterm, palliative measure under severe circumstances.

4. Foreign body sensitivity. A history or foreign body sensitivity may warrant against implantation as no pre-operative test can completely exclude the possibility of hypersensitivity or allergic reaction.

5. Smoking. Current or recent smokers tend to experience higher rates of fusion failure and are at higher risk for pseudarthrosis development. Smoking has also been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to recurring pain symptoms despite successful fusion and initial clinical improvement.

The **Apelo™ Pedicle Screw System** has a finite useful life. The patient's activity level has a significant impact on this useful life. Your patient must be informed that any activity increases the risk of loosening, bending, or breaking the implant.

Based on fatigue testing results, when using the **Apelo™ Pedicle Screw System**, 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 this system.

Contraindications:
The following specific contraindications, warnings, precautions and adverse effects should be understood fully by the physician and explained to the patient whenever relevant.

The **Apelo™ Spine Pedicle Screw System** is contraindicated in the presence of active systemic infection, open wounds, infection localized to the proposed surgical site and in cases where the patient has demonstrated allergic or foreign body sensitivity to any of the implanted materials.

Severe osteoporosis may prevent adequate fixation of screws and thus preclude the use of this or any other implanted orthopedic devices.

The **Apelo™ Spine Pedicle Screw System** is contraindicated in cases where the patient could be expected to achieve similarly satisfactory results using safer and/or predictable therapeutic alternatives.

Relative contraindications include conditions where excessive stresses may be placed on the bone and implants due to obesity, degenerative diseases, lifestyle, and/or psychological factors contributing to inability to properly adhere to restrictions in the immediate post-operative period.

In the presence of relative contraindications, the physician should weigh alternative risks and benefits when deciding whether a patient is a suitable candidate for these devices.

Warnings:
The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

Proper size selection. The potential for satisfactory fixation is increased

by the selection of the proper size, shape and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants.

Breakage. Implants are designed to load-share with adjacent bone to maintain alignment until normal healing occurs. The physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc. which may impact the performance of the system. If healing is delayed or does not occur, the implant may eventually break due to metal fatigue. The degrees of bony union, weight bearing, and activity levels influence the longevity of the implant.

Dissimilar metals. Dissimilar metals (e.g., titanium and stainless steel) should never be used when applying supplemental fixation to enhance the stability and preserve the alignment of The Apelo™ Pedicle Screw System. Internal fixation devices, such as rods, hooks, wires, and screws that come into contact with other metal objects must be made from like or compatible materials. There are many forms of corrosion damage and several of these occur on surgically implanted metals. General or uniform corrosion is present on all implanted metals and alloys and usually occurs at an acceptably slow rate due to the presence of passive surface films. Dissimilar metals in contact can accelerate this corrosion process which can, in turn, increase the risk of fatigue.

⚠ The Apelo™ Pedicle Screw System has not been evaluated for safety and compatibility in the MR environment. The Apelo™ Pedicle Screw System has not been tested for heating or migration in the MR environment.

Precautions:
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.

Combining Systems: Components of this system should not be used in conjunction with components of any other system or manufacturer.

Do Not Reuse: An explanted implant should never be re-implanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

Use Bone Graft: Internal orthopedic fixation devices cannot withstand activity levels equal to those placed on normal healthy bone and no implant can be expected to withstand indefinitely the unsupported stress of full weight bearing. These types of implants are more likely to fail if no bone graft is used or if a pseudarthrosis develops. Supplemental bone graft material is strongly recommended to help ensure the attainment of a solid fusion mass.

Postoperative Activity Restriction: Until maturation of the fusion is confirmed by radiographic examination, external immobilization (such as bracing) may be recommended, based on clinical judgment.

Provide Patient Instructions: The patient must be made aware of the limitations of internal fixation devices and the need for post-operative activity restrictions during the healing phase. The patient must be instructed in the limitations of the implant and should be warned regarding weight bearing and body stresses on the appliance prior to firm bone healing. The patient should be warned that noncompliance with postoperative instruction should lead to failure of the implant and possible need thereafter for additional surgery to remove the device.

Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and participation in sporting activities. The patient should understand that an implant is not as strong as normal bone. Excessive demands can loosen, bend and/or break the implant if excessive demands are placed on it, especially in the absence of complete bone healing.

Removal of Supplemental Fixation: The physician should carefully weigh the risks versus benefits if and when deciding whether to remove the system used to help maintain stability and alignment after placement. If the device is not removed after the completion of its intended use, any of the following complications may occur: corrosion, with localized tissue reaction or pain, migration of implant position resulting in injury, risk of additional injury from post-operative trauma, bending, loosening, and/or breakage, which could make removal impractical or difficult, pain, discomfort, or abnormal sensations due to the presence of the device, possible increased risk of infection, and bone loss due to stress shielding.

The possibility of, and the risks associated with, a second surgical procedure must also be discussed with the patient. When elected, removal of the system should be followed by adequate postoperative management to avoid refracture or deformity. If the patient is older and has a low activity level, the physician may choose not to remove the system thus eliminating the risks involved in a second surgery.

Potential Complications and Adverse Effects:
Complications arising from use of the Apelo™ Pedicle Screw System include the following:

1. Risks related to general anesthesia
2. Bending, fracture, or loosening of the implant
3. Sensitivity to the implant material
4. Allergic foreign body reaction
5. Early or late infection
6. Diminished bone density due to stress shielding
7. Pain, discomfort, or abnormal sensations due to the presence of the device
8. Nerve damage due to surgical trauma or the presence of the device
9. Neurological difficulties including bowel or bladder dysfunction, impotence, retrograde ejaculation, radicular pain, tethering of nerves in scar tissue, muscle weakness, and paresthesia
10. Vascular damage that could result in catastrophic bleeding, malpositioned implants or implant migration that could result in erosion of adjacent arteries or veins long after the initial postoperative period
11. Dural tears during the implantation procedure that could require further surgery for repair, chronic cerebrospinal fluid leak or fistula, and possible meningitis
12. Bursitis
13. Paralysis
14. Death
15. Spinal cord impingement or damage
16. Fracture of bony structures
17. Reflex sympathetic dystrophy
18. Degenerative changes or instability in segments adjacent to fused vertebral levels
19. Local osteolysis in articulating joints if pseudoarthrosis develops and leads to mechanical grinding and generation of wear debris.

Limited Warranty and Disclaimer: Atlas Spine, Inc. products are sold with a limited warranty to the original purchase against defects in workmanship and materials. Any other expressed or implied warranties including warranties of merchantability or fitness are hereby disclaimed.

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

Atlas Spine, Inc.
1555 Jupiter Park Drive, Suite #4
Jupiter, FL 33458
Tel. 561-741-1108

NON STERILE NON-STERILE

WARNING: Single Use. Do Not Resterilize or Industrially Process Component for Re-Use, as this May Cause Damage or Deterioration of the Component.

NOTES

Atlas Spine Inc., 1555 Jupiter Park Drive, Suite 4 Jupiter, FL 33458 www.atlasspine.com Ph. 561-741-1108 Fx. 561-741-1870