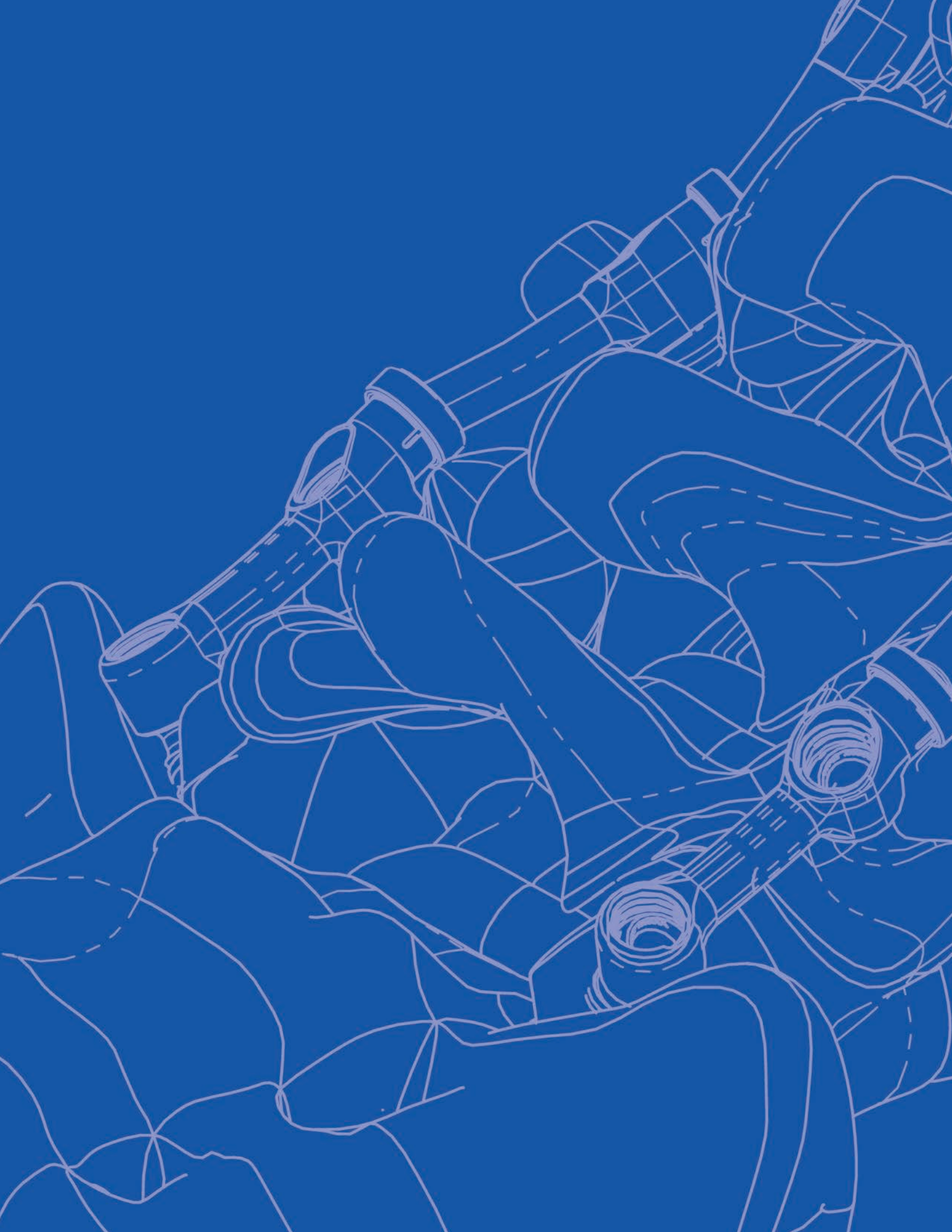
PressON™

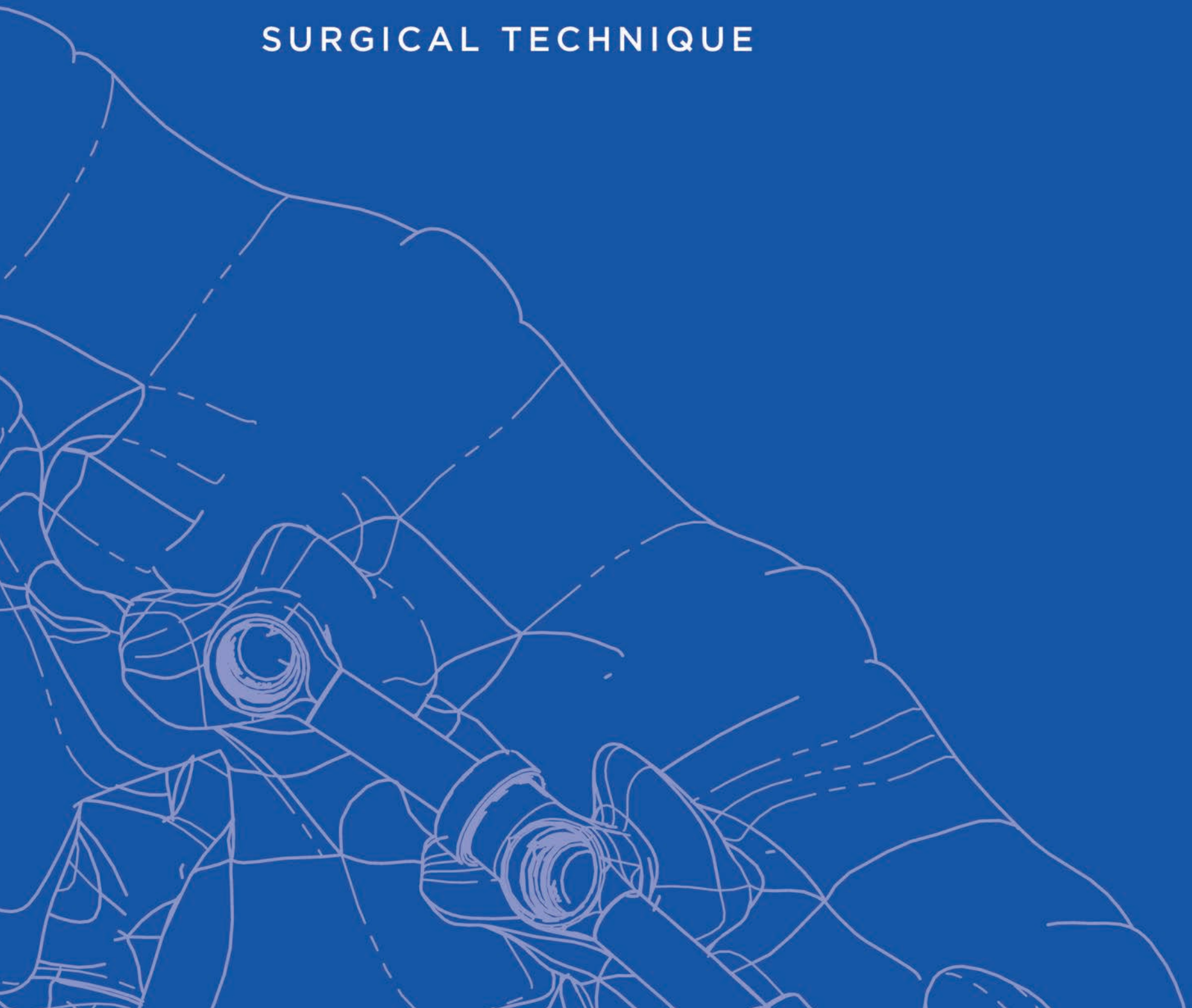
SPINAL FIXATION SYSTEM

TRADITIONAL MIDLINE SURGICAL TECHNIQUE GUIDE

CONTENTS



SURGICAL TECHNIQUE



INTRODUCTION

The PressON™ Spinal Fixation System from Nexus Spine employs fixed-length constructs, wherein modular assemblies accommodate patient-specific needs.

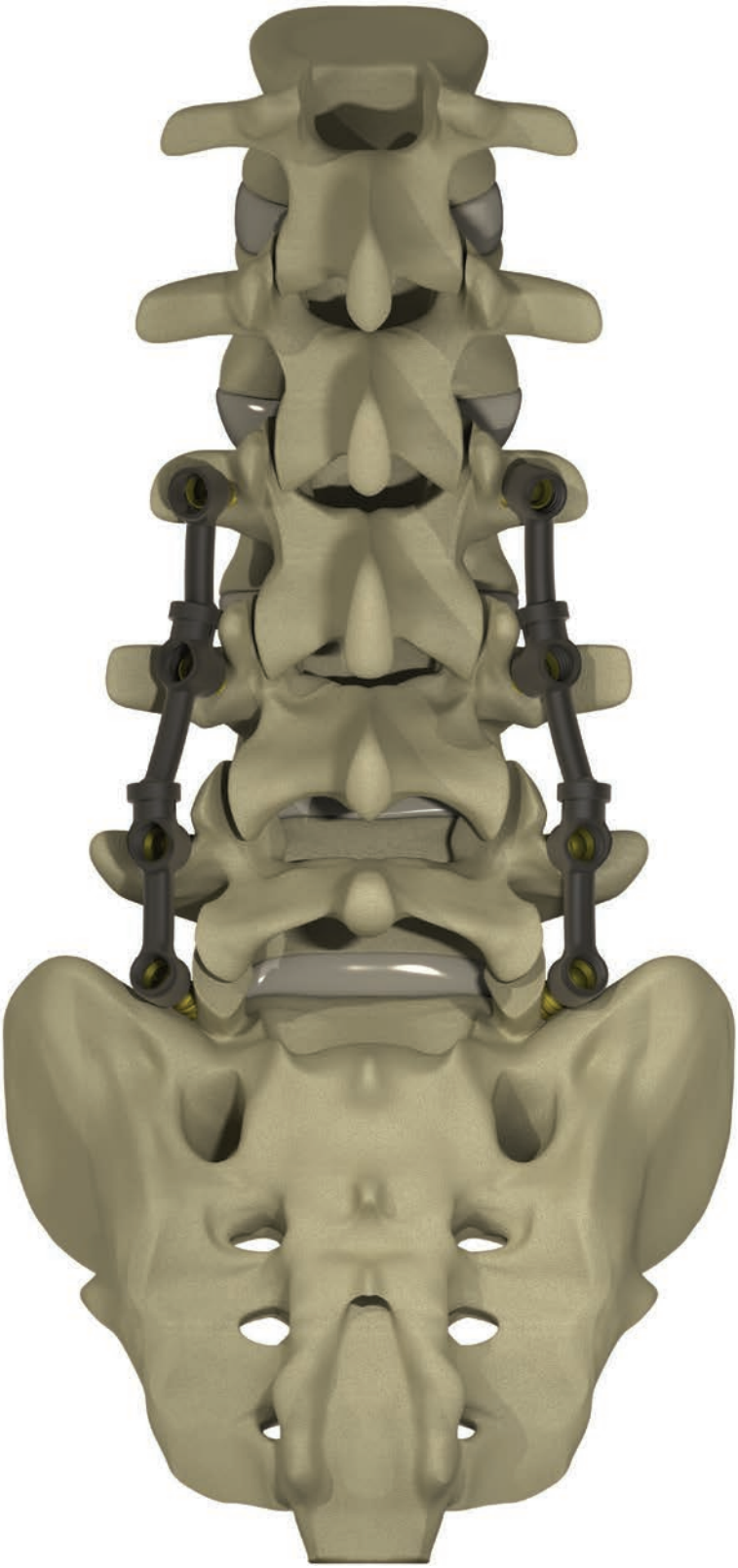
This novel design is:

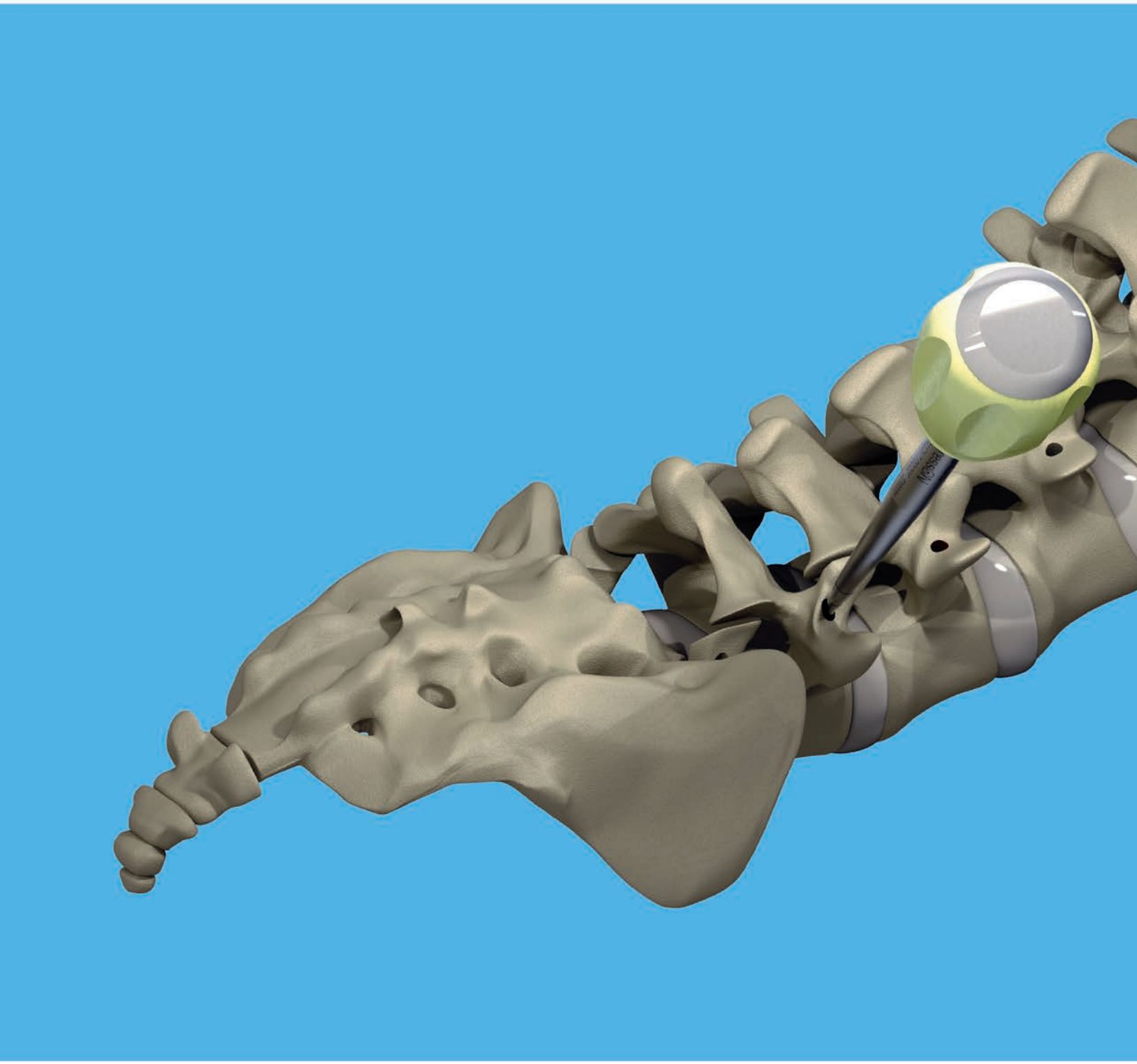
- lower profile
- faster to implant
- simple to use
- free of cross-threading

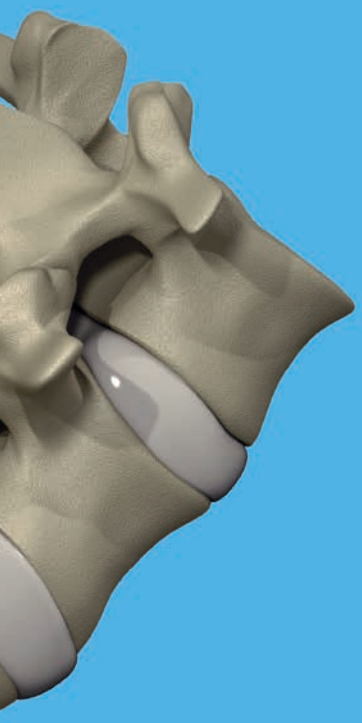
The PressON system is cannulated. One set of instruments accommodates several surgical approaches.

- Traditional mid-line
- Limited-exposure cortical
- Modified Wiltse
- Percutaneous

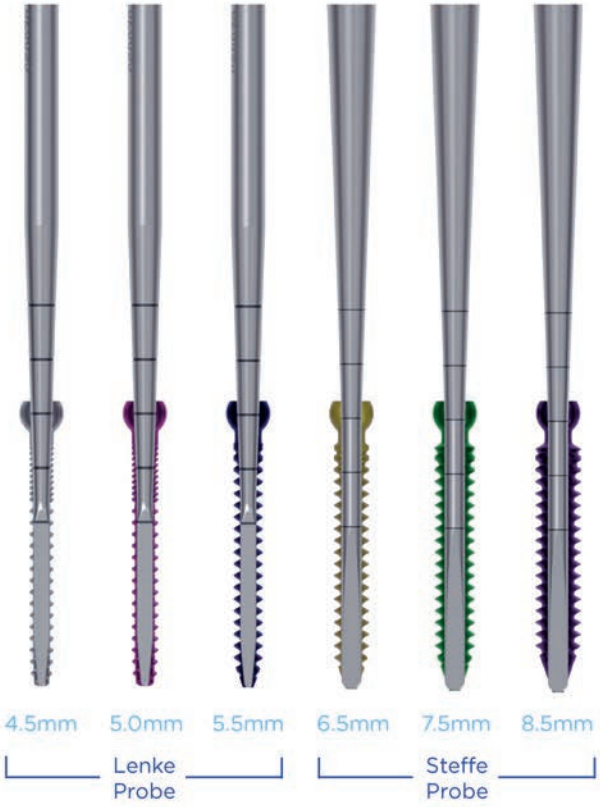
This surgical technique guide assumes a full-length, midline surgical incision. For other surgical approaches (e.g. percutaneous implantation) please request one of our other surgical technique guides.







PEDICLE PREPARTION



PROBE

Match the pedicle probe to the minor diameter of the Screw.

A Steffe Probe or a Lenke Probe is immediately available with the set. Please express your preference. We can acquire most styles of probes and handles. Please allow 6 to 8 weeks for custom requests.

Note: A Lenke Probe is small enough in diameter to be used with 4.5mm, 5.0mm, and 5.5mm diameter Screws.

PEDICLE PREPARATION CONTINUED

TAPS

The Taps are sized to nominal. If undertapping is desired, then choose a Tap with a smaller nominal size.

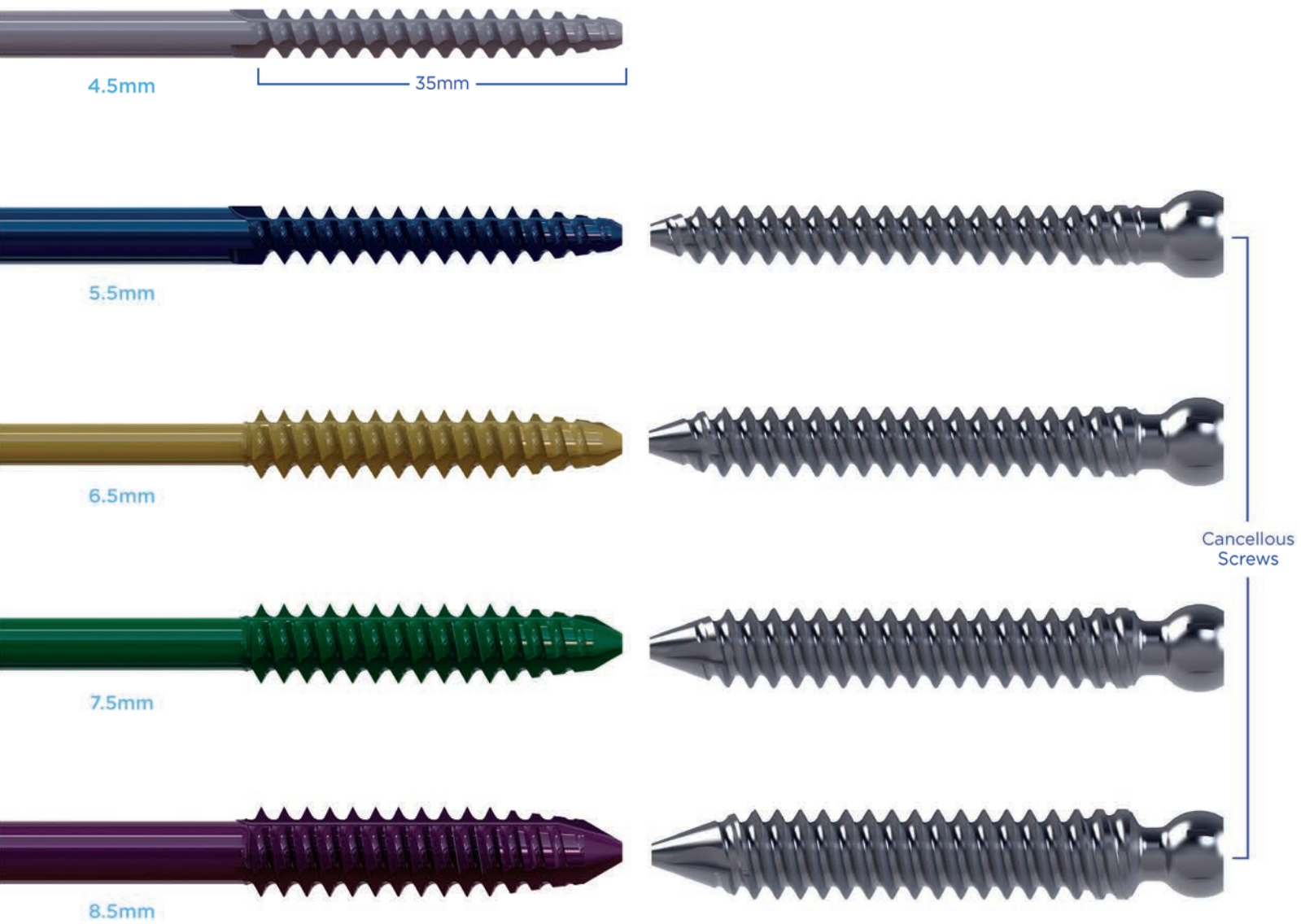
The threads on the Taps match those on the Screws. For exact specifications, see Implant Specifications for Cortical and Cancellous Screws below.

4.0mm

4.5mm

5.0mm

Cortical Screws


4.5mm
35mm
5.5mm
6.5mm
7.5mm
8.5mm
Cancellous
Screws

DRIVER-TO-SCREW ATTACHMENT

STEP 1

The Internal Retaining Driver is shown here fully extended and ready to receive a Screw.

STEP 2

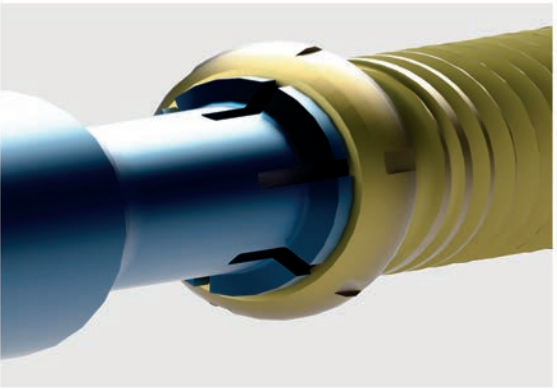
With the Driver fully extended, grasp and hold its blue portion and snap a Screw onto its split tip.

STEP 3

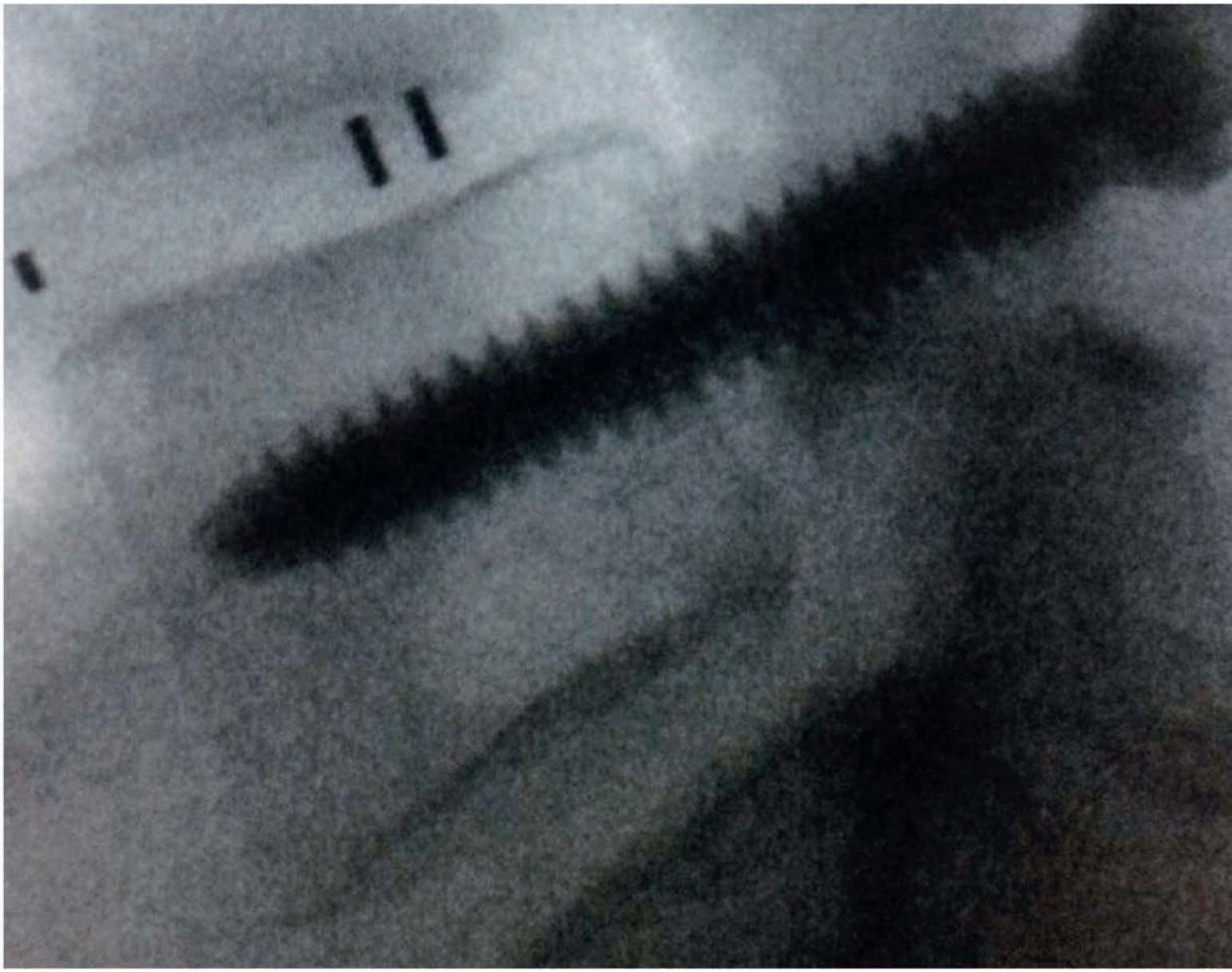
Rotate the black portion of the Driver until the hexalobe features are aligned.

STEP 4

With the hexalobe features aligned and while grasping and holding the blue sleeve, push the black part of the Driver forward until it clicks closed.



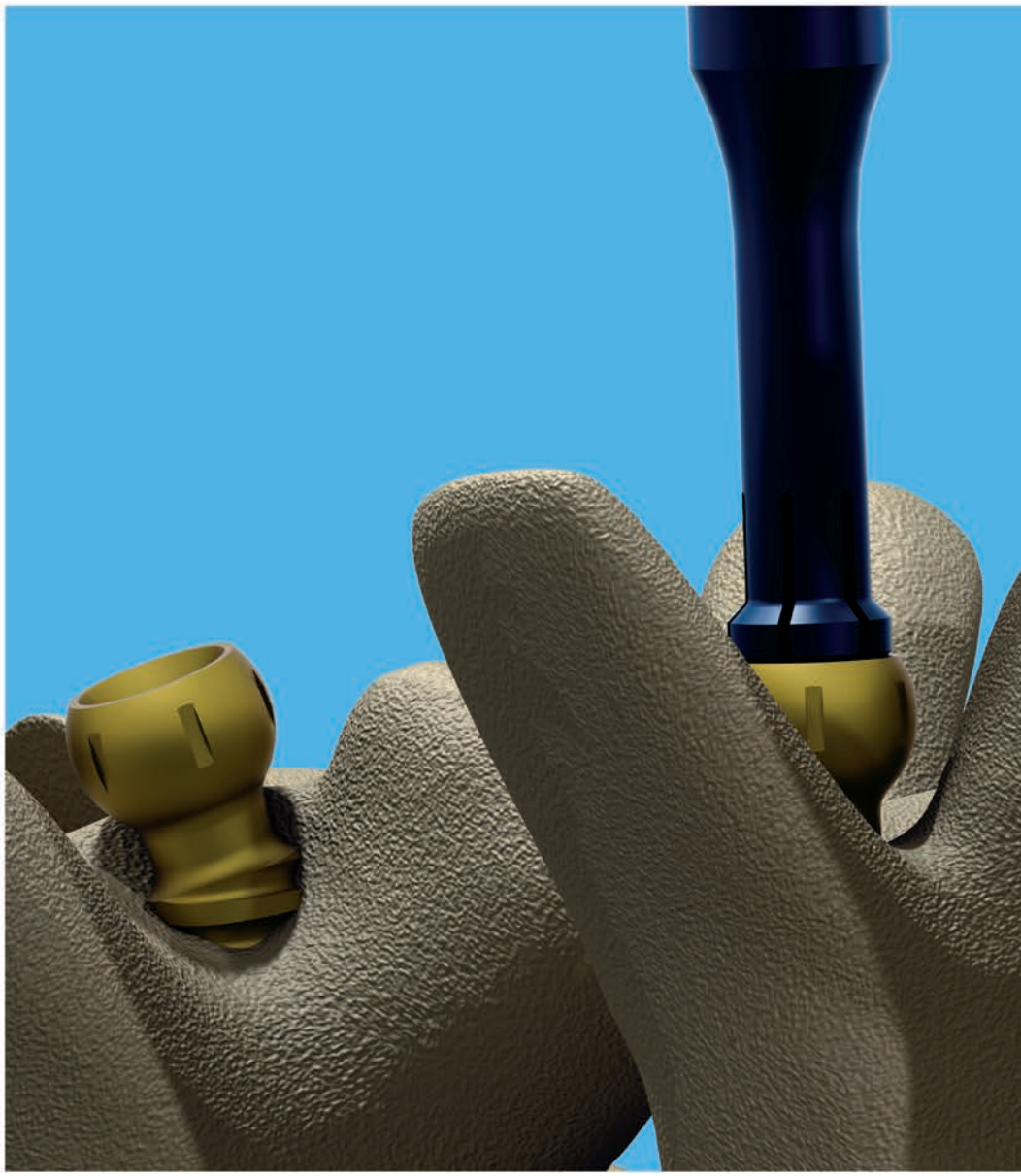
PEDICLE SCREW INSERTION

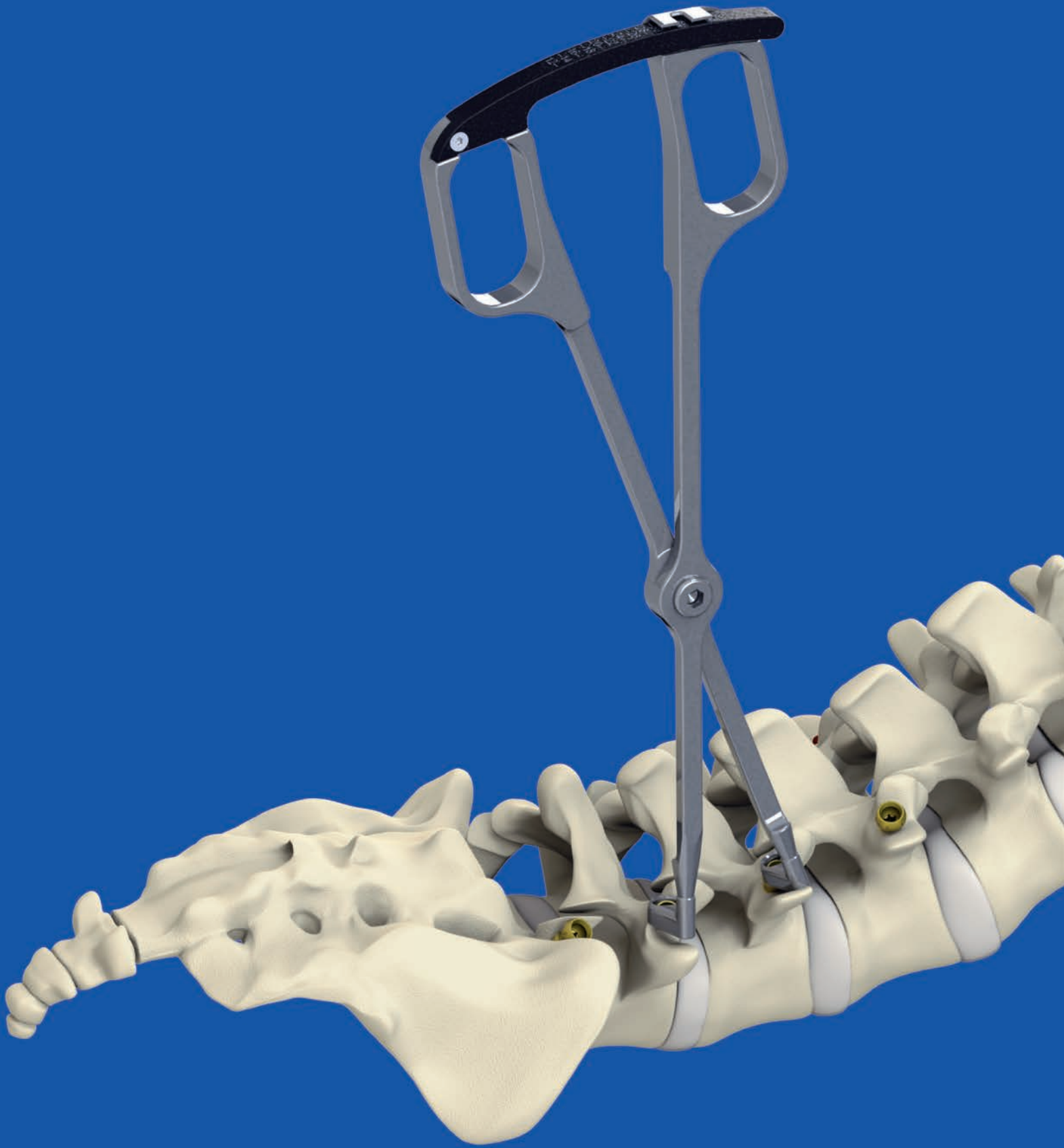


When implanted, the Screw should extend 50-80% into the vertebral body and be parallel to the superior endplate. For sacral fixation, bicortical purchase may be utilized.

The Rod can be locked to the Pedicle Screw regardless of the depth of the Pedicle Screw in the bone as long as the equator of the Screw head is exposed. However, it would be unusual to drive the unthreaded neck of the Screw into the bone.

Note: The location of Screw placement is largely dictated by surgical exposure. Be aware of how low the Rod will sit to the bone when setting Screw depth. Some locations will allow the Screws to sit closer to the bone without risk of the ultra-low-profile Rod hitting an articular process.



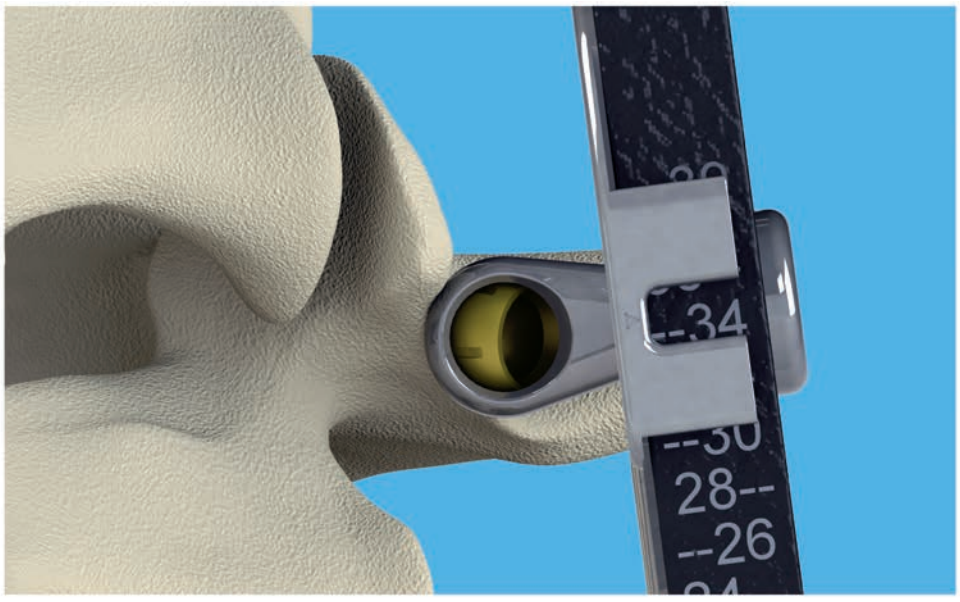


ROD SIZING

CALIPERS

Measure the distance between Screw centers.

Ensure that a neutral measurement is taken with no force applied to the Pedicle Screws.



In this picture the measurement reads approximately 34mm.

FIXED-LENGTH ROD SELECTION

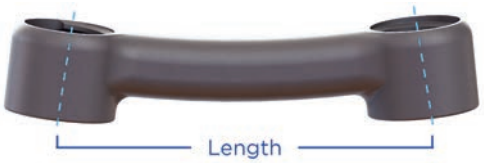
Select the Rod that best corresponds with the Calipers measurement.

Drive Screws slightly in or out to optimize Rod fit as each half turn of a Screw yields about 0.5mm of length adjustment.

Select a Rod shorter or longer than the Calipers measurement in order to compress or distract, respectively.

Note: All listed Rod lengths represent distances between screw coupler centers.

1-LEVEL FIXED-LENGTH ROD



LENGTH

12mm	2mm Increment
14mm	
16mm	
18mm	
20mm	
22mm	
24mm	
26mm	
28mm	
30mm	
32mm	
34mm	
36mm	

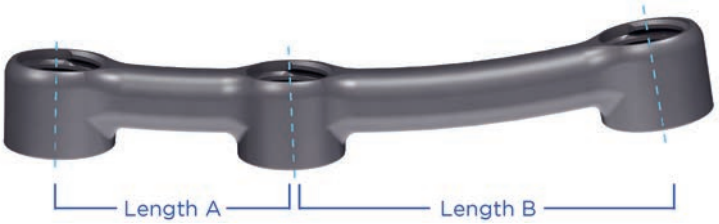
LENGTH

39mm	3mm Increment
42mm	
45mm	
48mm	
51mm	
54mm	
57mm	
60mm	

LENGTH

62.5mm	2.5mm Increment
65mm	
67.5mm	
70mm	
72.5mm	
75mm	
77.5mm	
80mm	

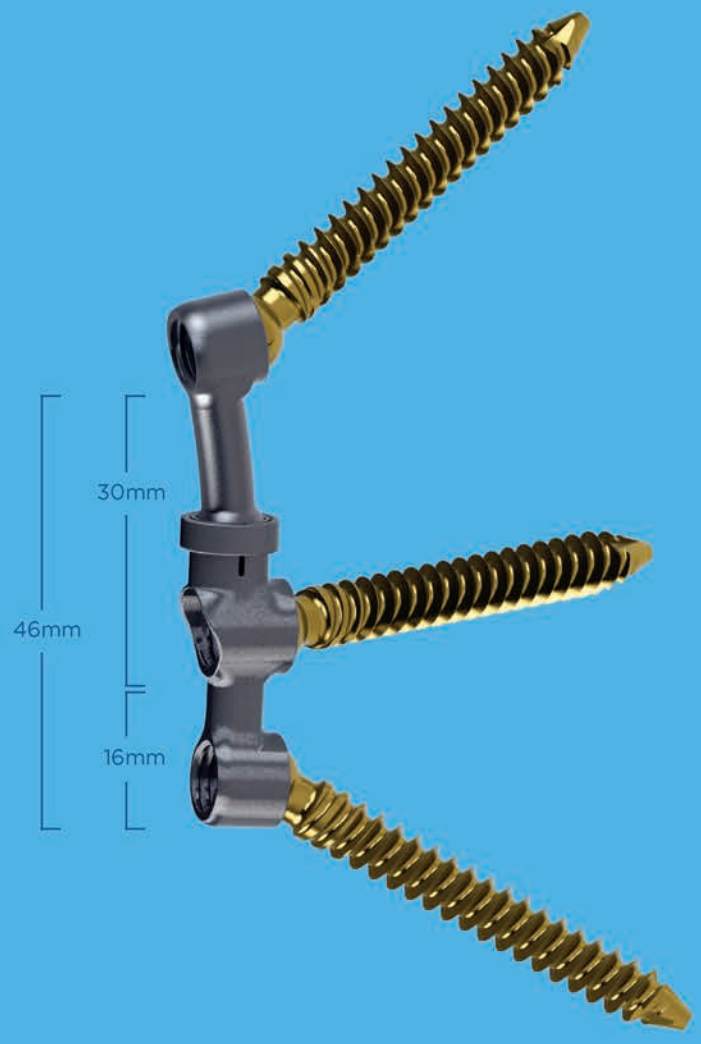
2-LEVEL FIXED-LENGTH ROD



LENGTH A

LENGTH B	12	14	16	18	20	22	24	27	30	33	36
12	12x12	12x14	12x16	12x18	12x20	12x22	12x24	12x27	12x30	12x33	12x36
15		15x14	15x16	15x18	15x20	15x22	15x24	15x27	15x30	15x33	15x36
18			18x16	18x18	18x20	18x22	18x24	18x27	18x30	18x33	18x36
21				21x18	21x20	21x22	21x24	21x27	21x30	21x33	21x36
24					24x20	24x22	24x24	24x27	24x30	24x33	24x36
27						27x22		27x27	27x30	27x33	27x36
30									30x30	30x33	30x36
33										33x33	33x36
36											36x36

MULTI-LEVEL ROD SELECTION



Multi-Level Rods are built intra-operatively.

Select the combination of Multi-Level Components that best corresponds with the Calipers measurements.

Drive screws slightly in or out to optimize fit as each half turn of a Screw yields about 0.5mm of length adjustment.

Select Rods shorter or longer than the Calipers measurements in order to compress or distract, respectively.

Note: Be cognizant of the sum of the Rod lengths. For example, if the Calipers measurements total 46mm, then the sum of the parts should be close to 46mm.

DOUBLE COUPLER

LENGTH

- 12mm
- 14mm
- 16mm
- 18mm
- 20mm
- 22mm
- 24mm
- 26mm
- 28mm
- 30mm
- 32mm
- 34mm
- 36mm
- 39mm
- 42mm
- 45mm
- 48mm
- 51mm
- 54mm
- 57mm
- 60mm
- 62.5mm
- 65mm
- 67.5mm
- 70mm
- 72.5mm
- 75mm
- 77.5mm
- 80mm

HYBRID ROD

LENGTH

- 18mm
- 20mm
- 22mm
- 24mm
- 26mm
- 28mm
- 30mm
- 32mm
- 34mm
- 36mm
- 39mm
- 42mm
- 45mm
- 48mm
- 51mm
- 54mm
- 57mm
- 60mm
- 62.5mm
- 65mm
- 67.5mm
- 70mm
- 72.5mm
- 75mm
- 77.5mm
- 80mm

L-ROD

LENGTH

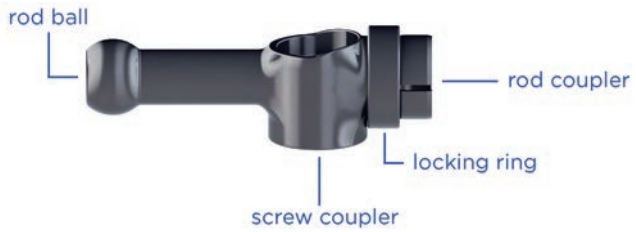
- 18mm
- 20mm
- 22mm
- 24mm
- 26mm
- 28mm
- 30mm
- 32mm
- 34mm
- 36mm
- 39mm
- 42mm
- 45mm
- 48mm
- 51mm
- 54mm
- 57mm
- 60mm
- 62.5mm
- 65mm
- 67.5mm
- 70mm

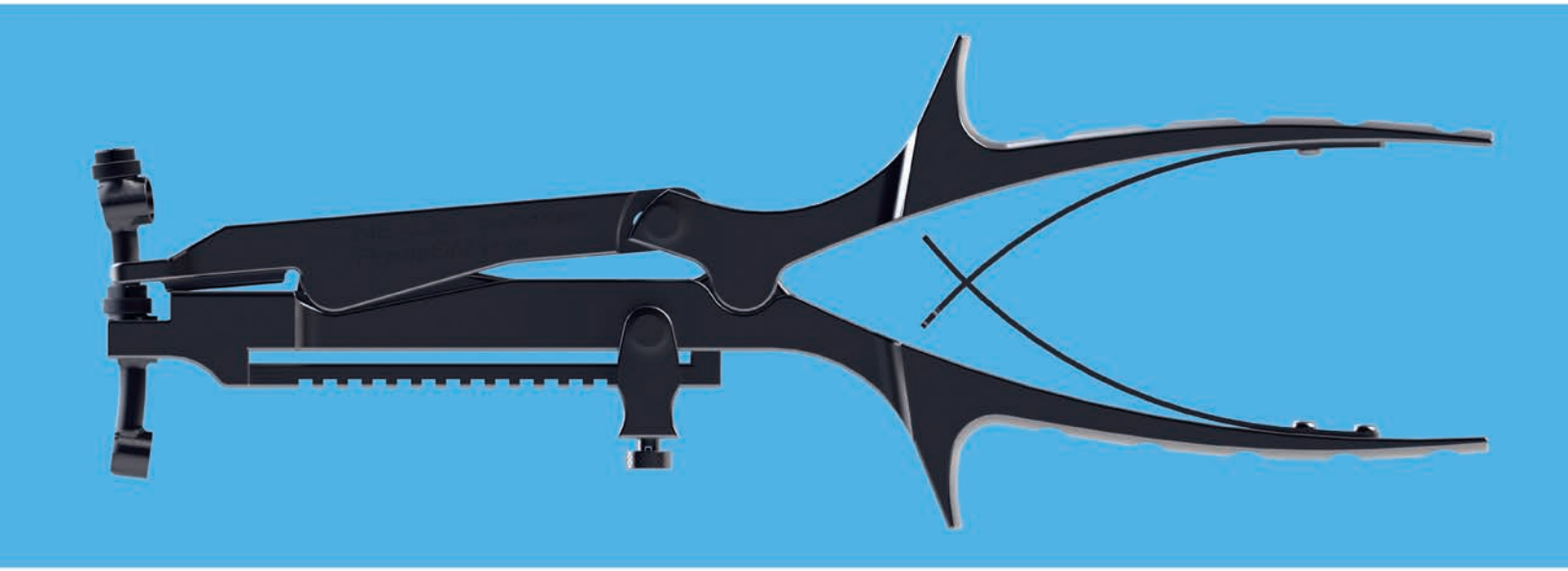
MULTI-LEVEL ROD ASSEMBLY

The Construct Builder connects the Multi-Level Rods into an unlocked, free-to-pivot state.

Place the screw coupler of the Rod that is to receive a rod ball onto the post of the Construct Builder.

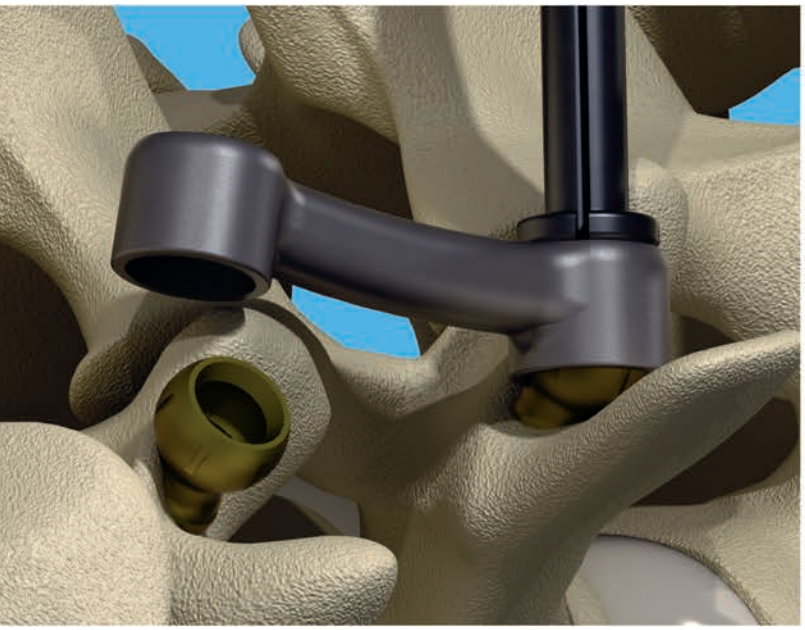
Place the rod ball of the second Rod into the yoke of the Construct Builder.





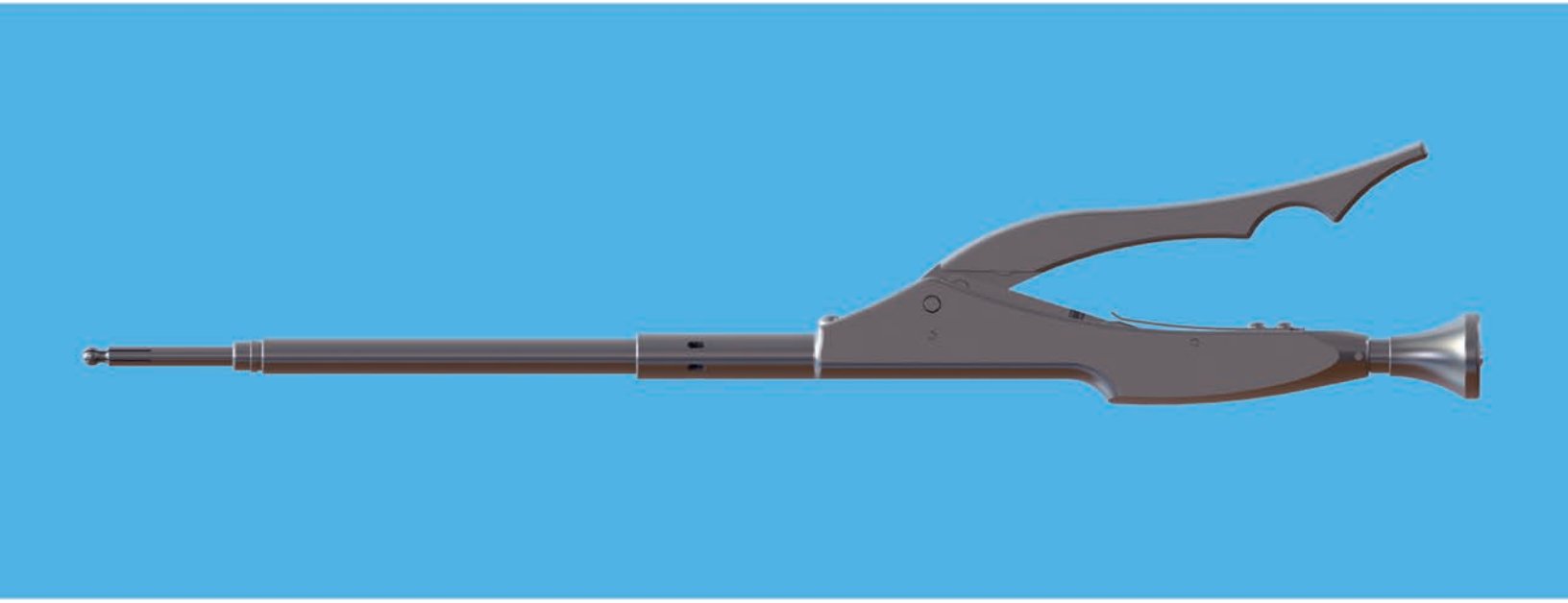
Squeeze the Construct Builder to assemble the Multi-Level Rods. The Rods cannot be pulled apart by hand, but will freely pivot under light pressure.

ROD INSERTION



Use the Rod Holder to insert the Rod and hold down the free end while locking.

SCREW LOCKING



Open the trigger of the Screw Locker completely to ensure proper assembly with the Pedicle Screw.

Push the tip of the Screw Locker through the Rod screw coupler and into the bore in the head of the Pedicle Screw. The tip will lightly pop as it fully seats.

Ratchet the Screw Locker down until the tip of the barrel is contacting the Rod. Pull up on the Screw Locker to verify the attachment.

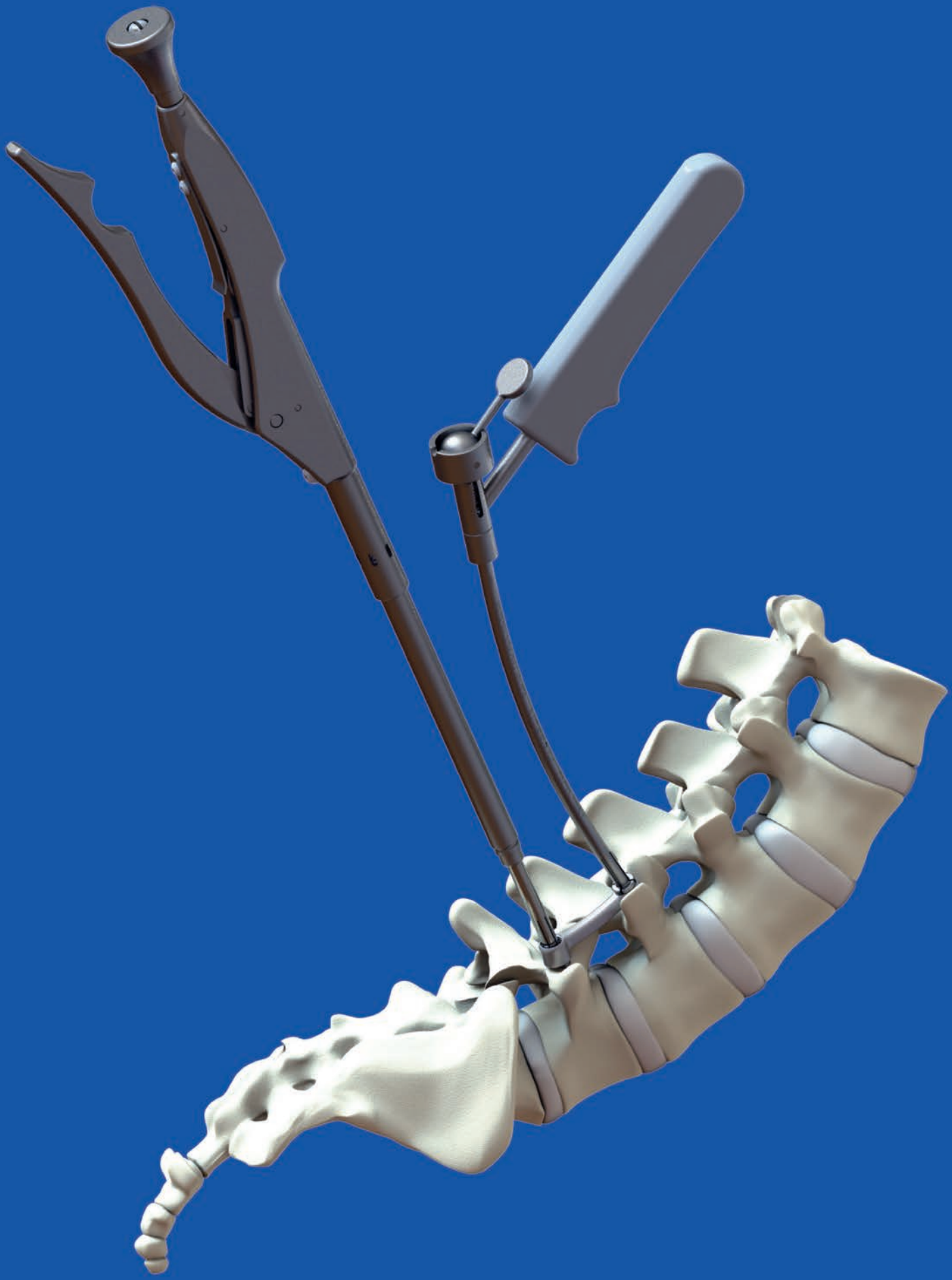
SCREW LOCKING CONTINUED ON NEXT PAGE

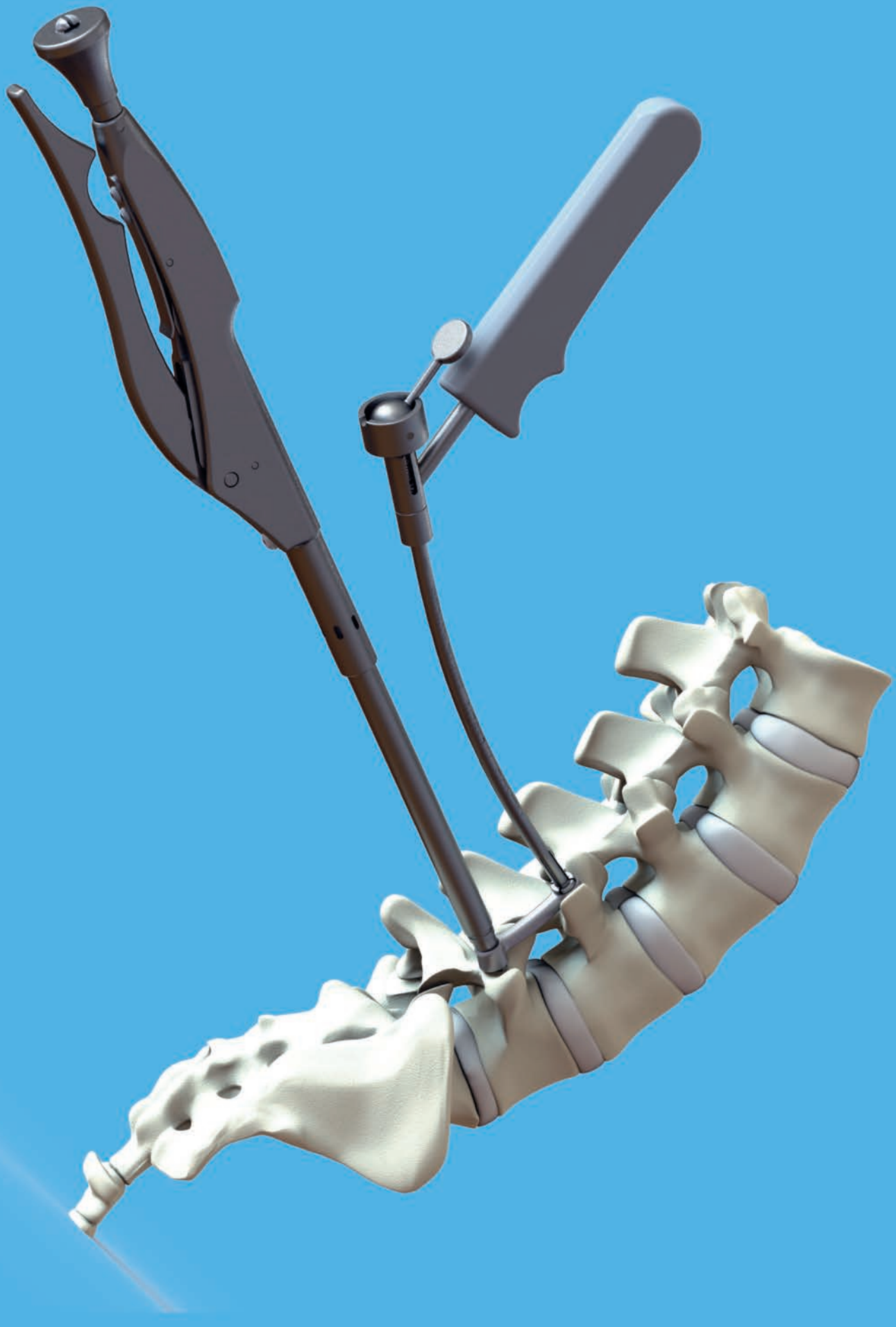
SCREW LOCKING CONTINUED

Using the Rod Holder, be careful while locking the first end of the Rod to keep the other end contacting its Screw.

Continue ratcheting the Screw Locker. Once you feel some resistance on the trigger, you have begun Screw locking.

SCREW LOCKING CONTINUED ON NEXT PAGE





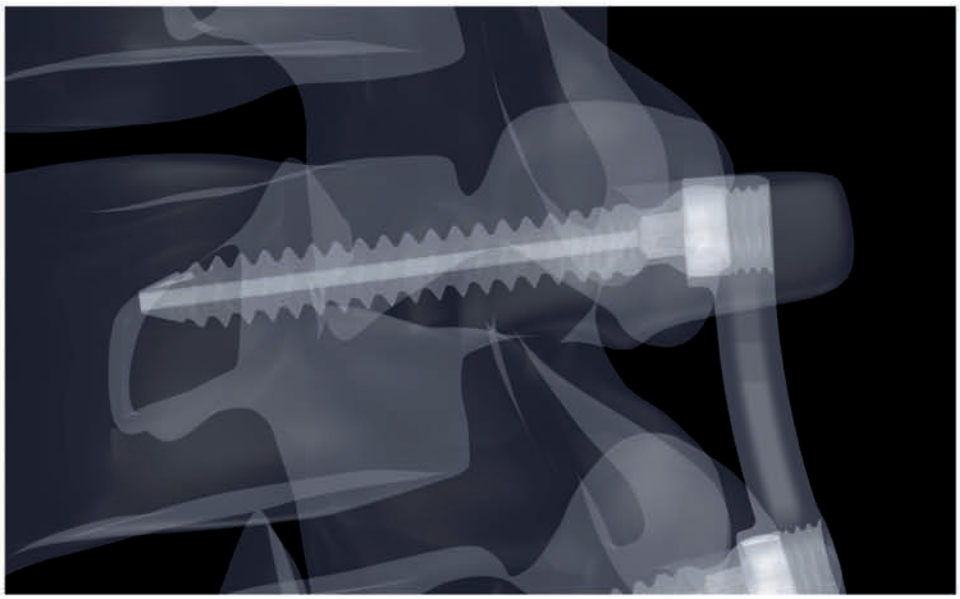
SCREW LOCKING CONTINUED

Continue ratcheting the Screw Locker until:
- Trigger is completely closed and
- Lock indicator is protruding.

The Screw and Rod are now locked.

Release and remove the Rod Holder.

To release the Screw Locker, use two hands to fully open the trigger.



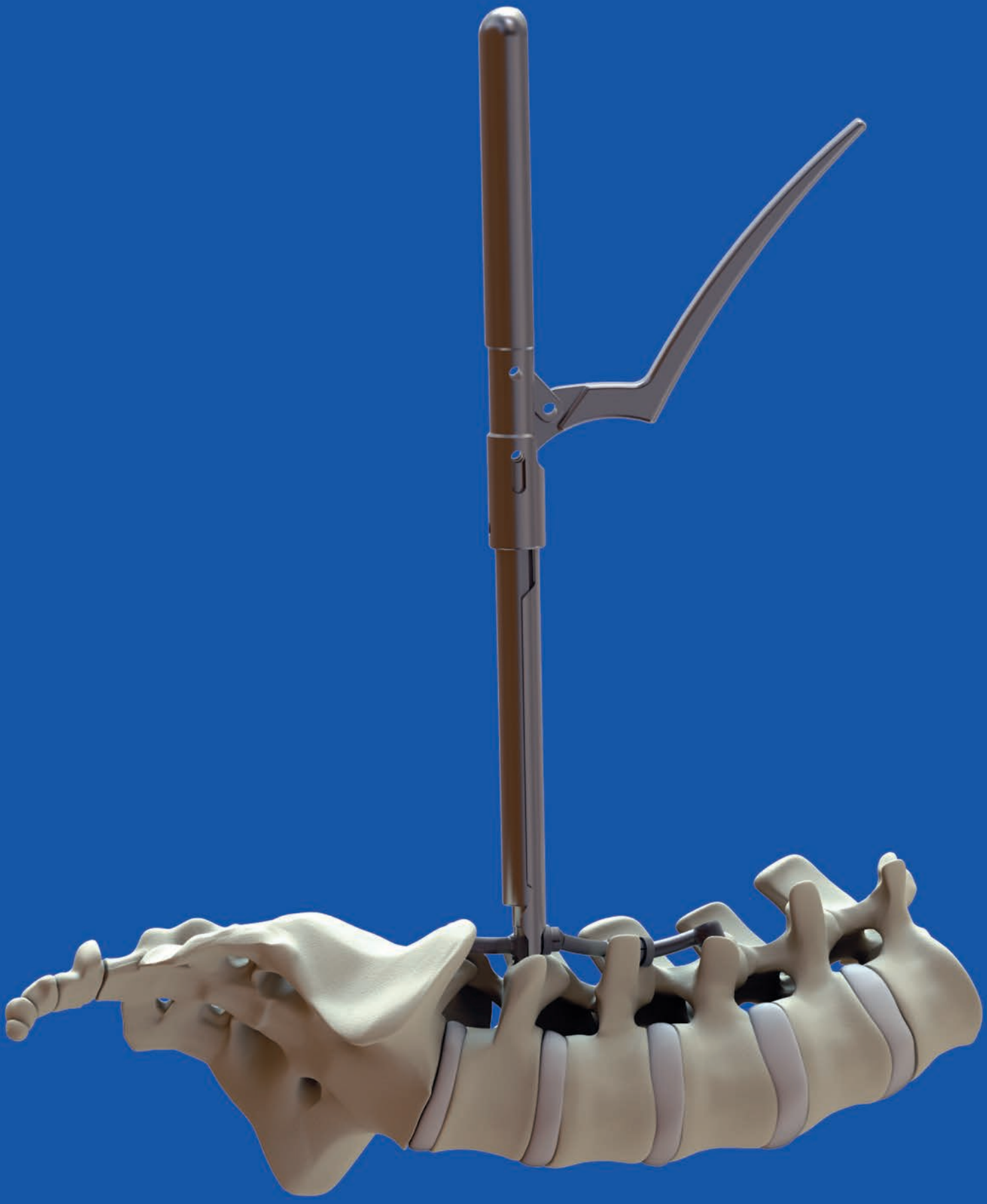
Note: Screw lock can be verified on x-ray. Final, intra-operative x-ray is recommended to verify that every Rod's screw coupler is around the head of its corresponding Pedicle Screw.

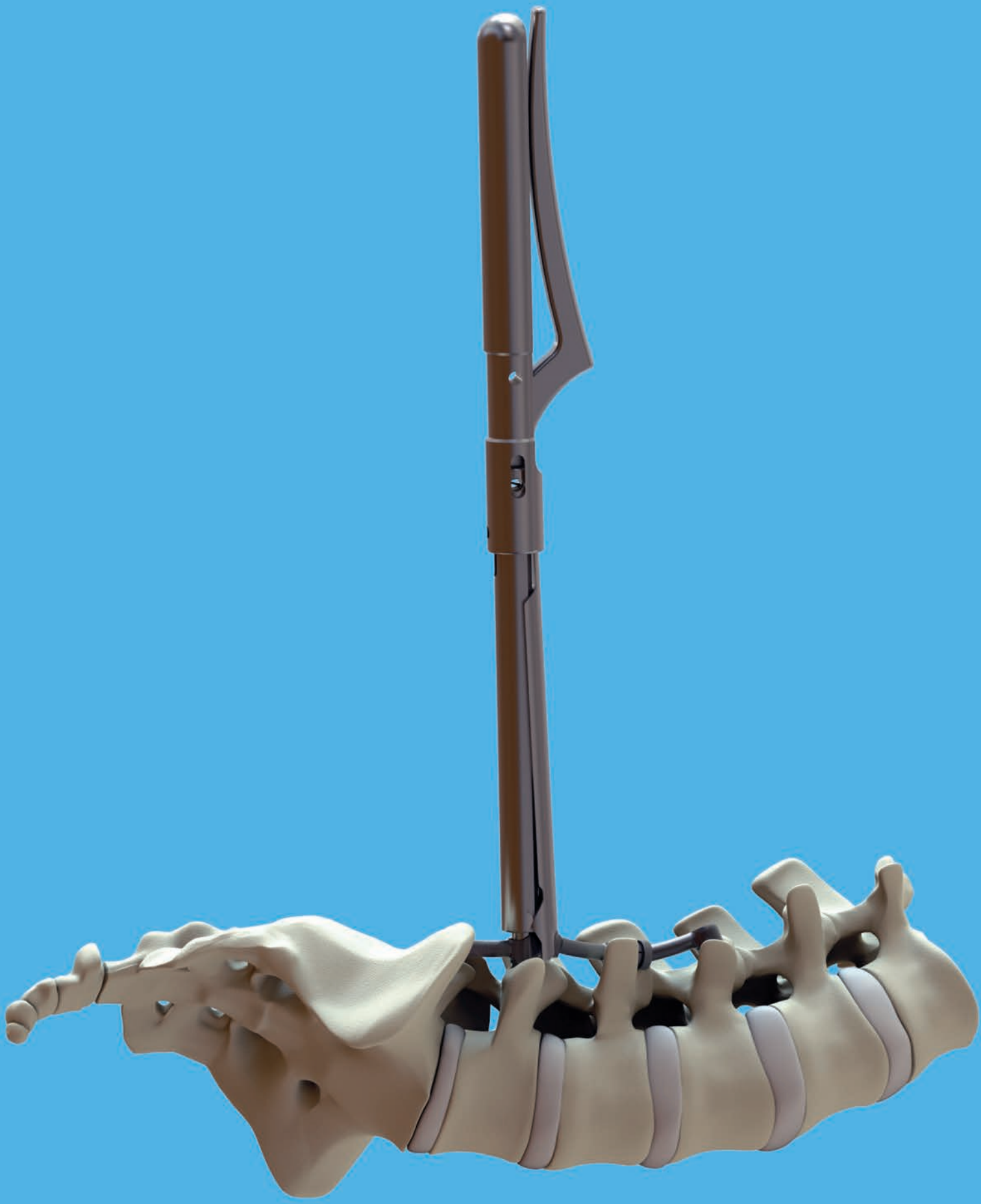
ROD LOCKING

The Screw-to-Rod interface of all Rods allows 52 degrees of polyaxial motion. The Rod-to-Rod interface of Multi-Level Rods provides an additional 40 degrees of polyaxial motion. Once locked, each interface is rigid.

Rod locking can be done before or after Screw locking. If done first, then the subsequent Screw locking can manipulate the spine, such as when reducing a spondylolisthesis. If done second, then the Rod will adapt its form to that of the spine.

ROD LOCKING CONTINUED ON NEXT PAGE





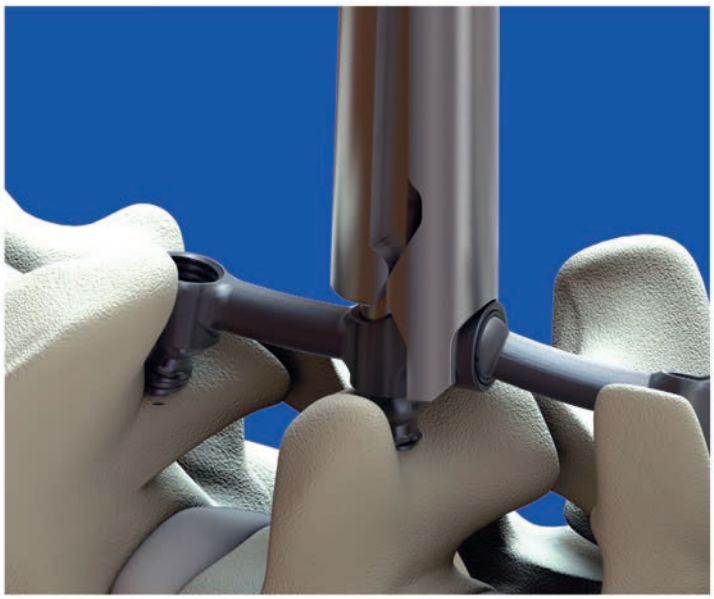
ROD LOCKING CONTINUED

Fully seat the Rod Locker on the Rod, with the cylinder tip inserted into the top of the screw coupler, and the forked tip inserted between the screw coupler and locking ring.

Squeeze the handle until fully closed. The forked tip will slide the locking ring over the rod coupler.

The Rods are now locked. Pull the handles apart to release.

Note: The Rod is fully locked when any portion of the locking ring reaches the end of the rod coupler.



SCREW UNLOCKING

Insert the Counter Torque over the screw coupler to be unlocked.

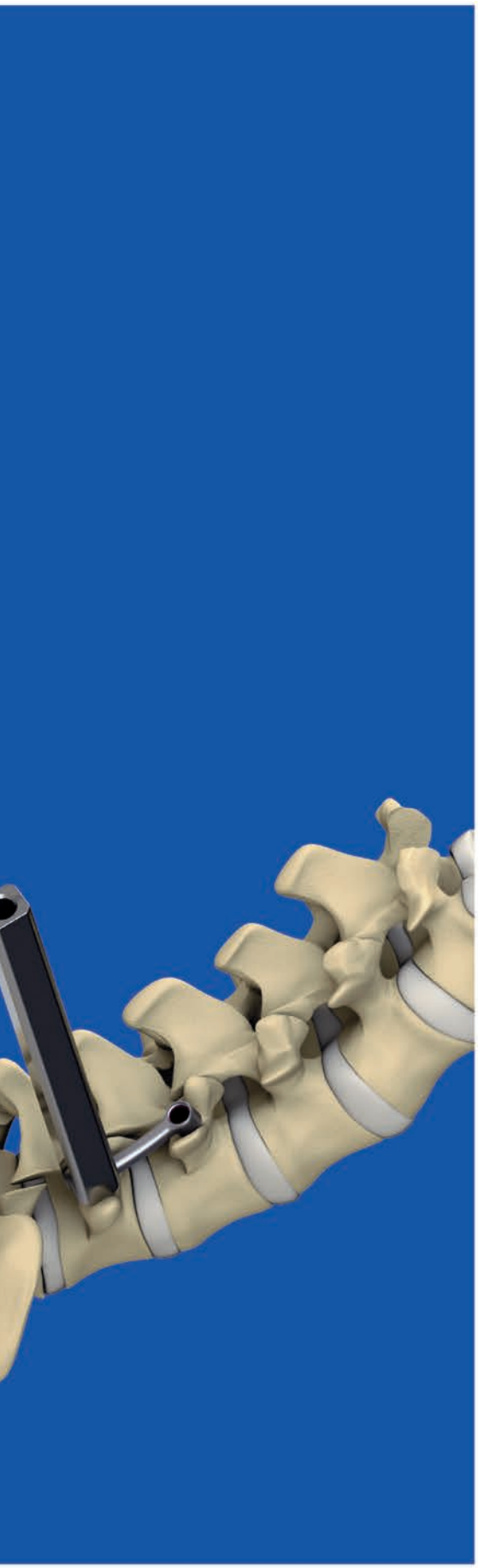
Thread the Screw Unlocker clockwise into the screw coupler with the Ratcheting T-Handle.

Significant torque will be required for two full revolutions of the Screw Unlocker.

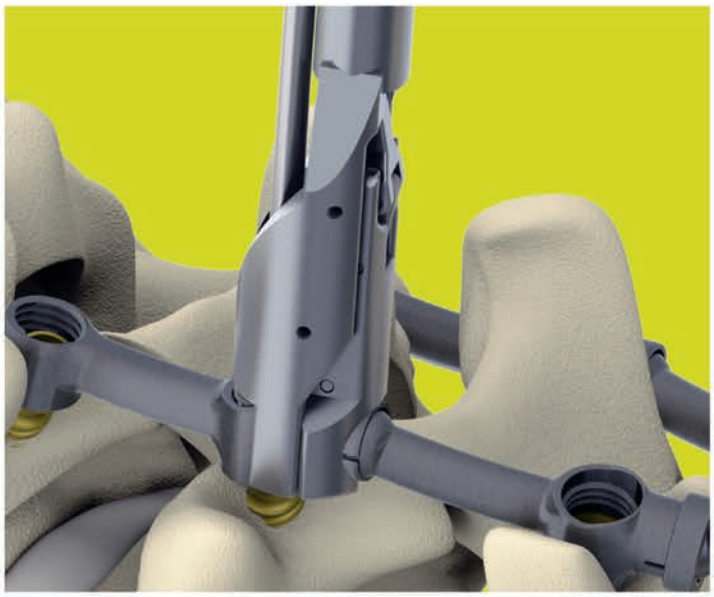
A sudden drop in torque will indicate Screw unlock is complete.

Note: Relocking the same Screw and screw coupler results in a ≈30% decrease in the strength of the lock. Relocking once is allowable but with caution. Relocking twice is strongly discouraged. It is best to replace any Rod that has been unlocked.

Note: The Pedicle Screws can be left in place and relocked to new Rods; the Pedicle Screws do not see degradation with unlocking. Still, repeated relocking is not recommended.



ROD UNLOCKING

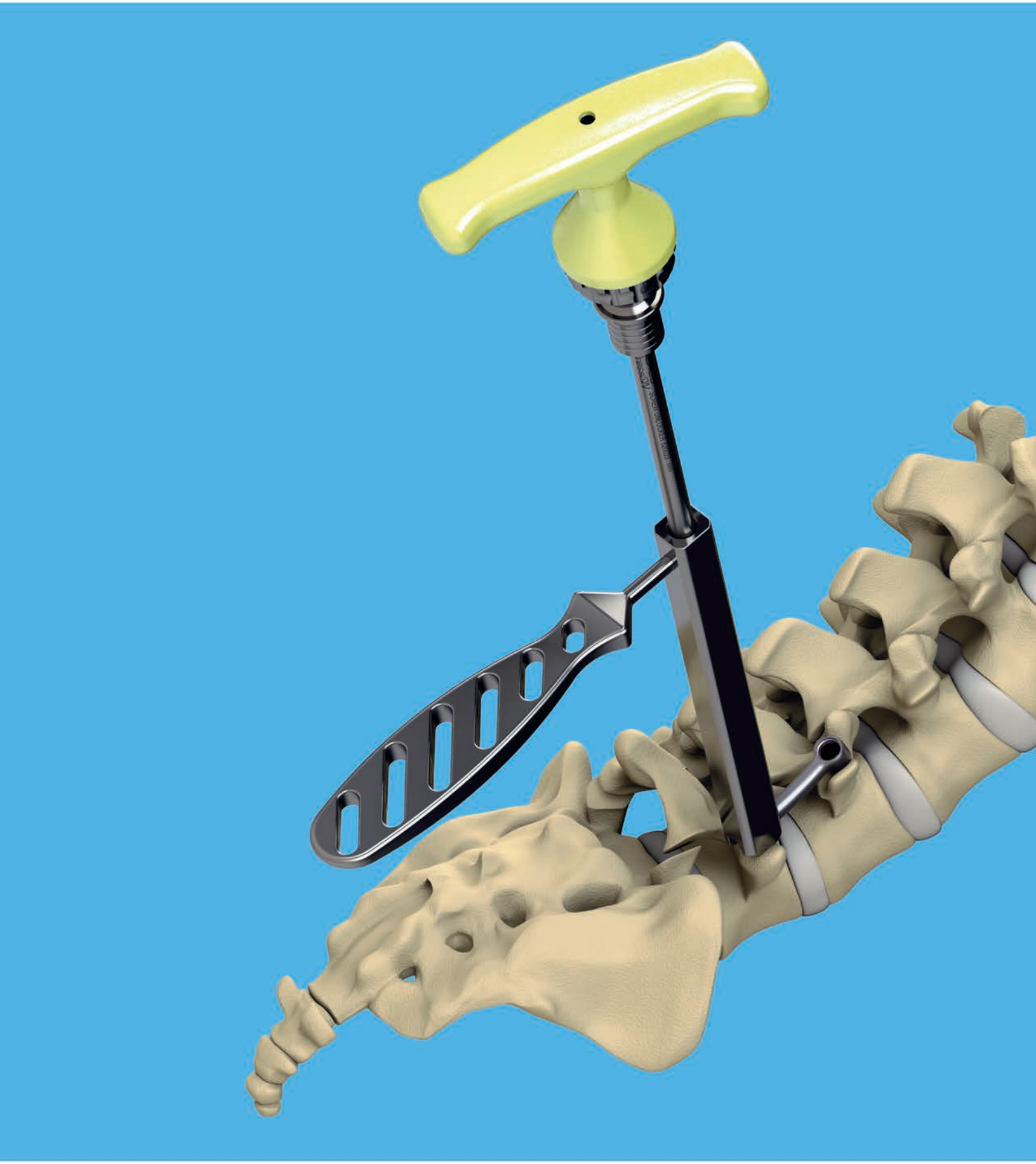


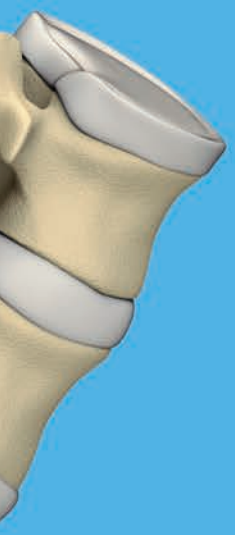
Insert the guide shaft into the top of the screw coupler.

Slide the Rod Unlocker over the guide shaft with the fingers spread apart until fully seated on the Rod.

Using the T-bar as a counter torque, turn the handle clockwise to pull the locking ring toward the screw coupler.

Note: Relocking the same Rod results in a decrease in lock strength. Relocking is strongly discouraged.



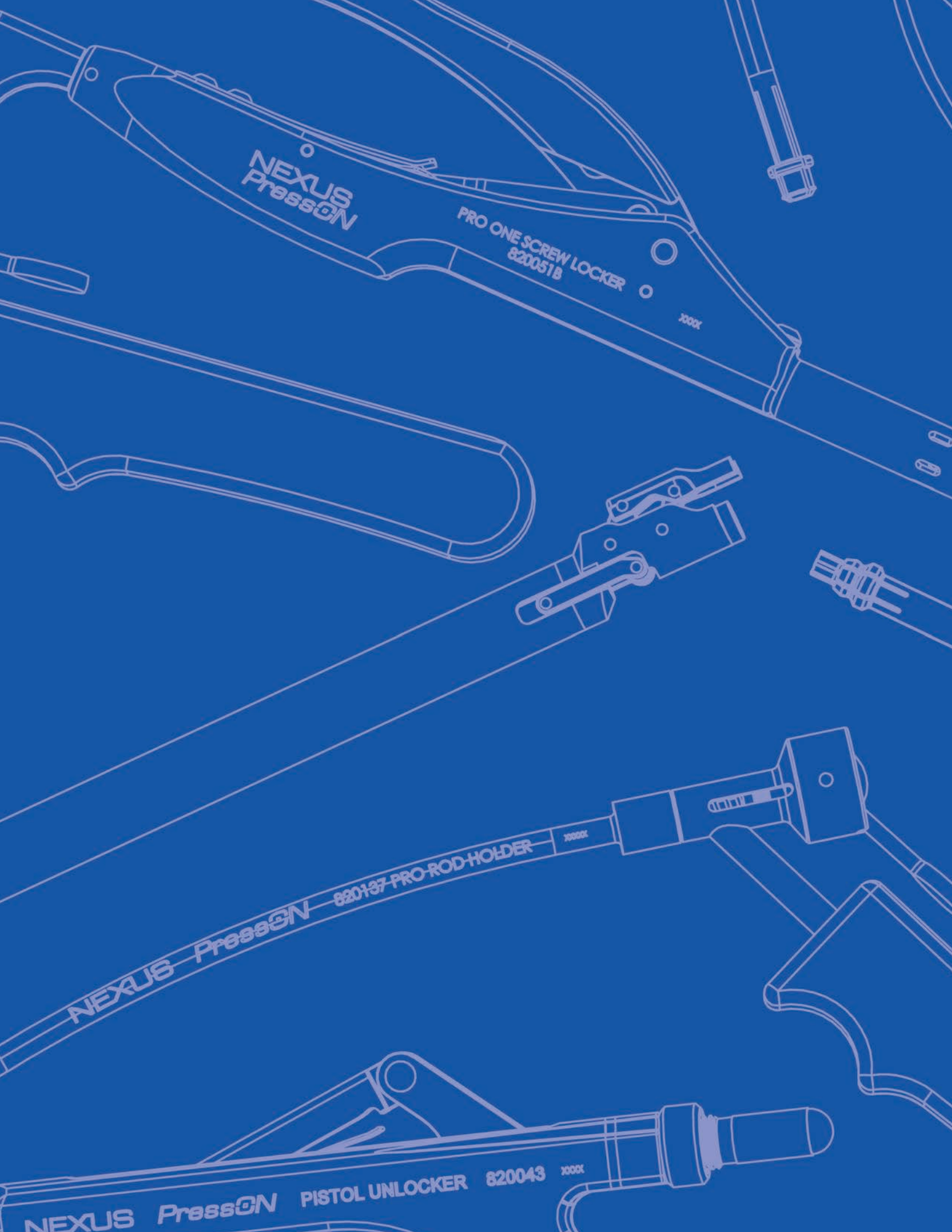


REMOVAL OF CONSTRUCT

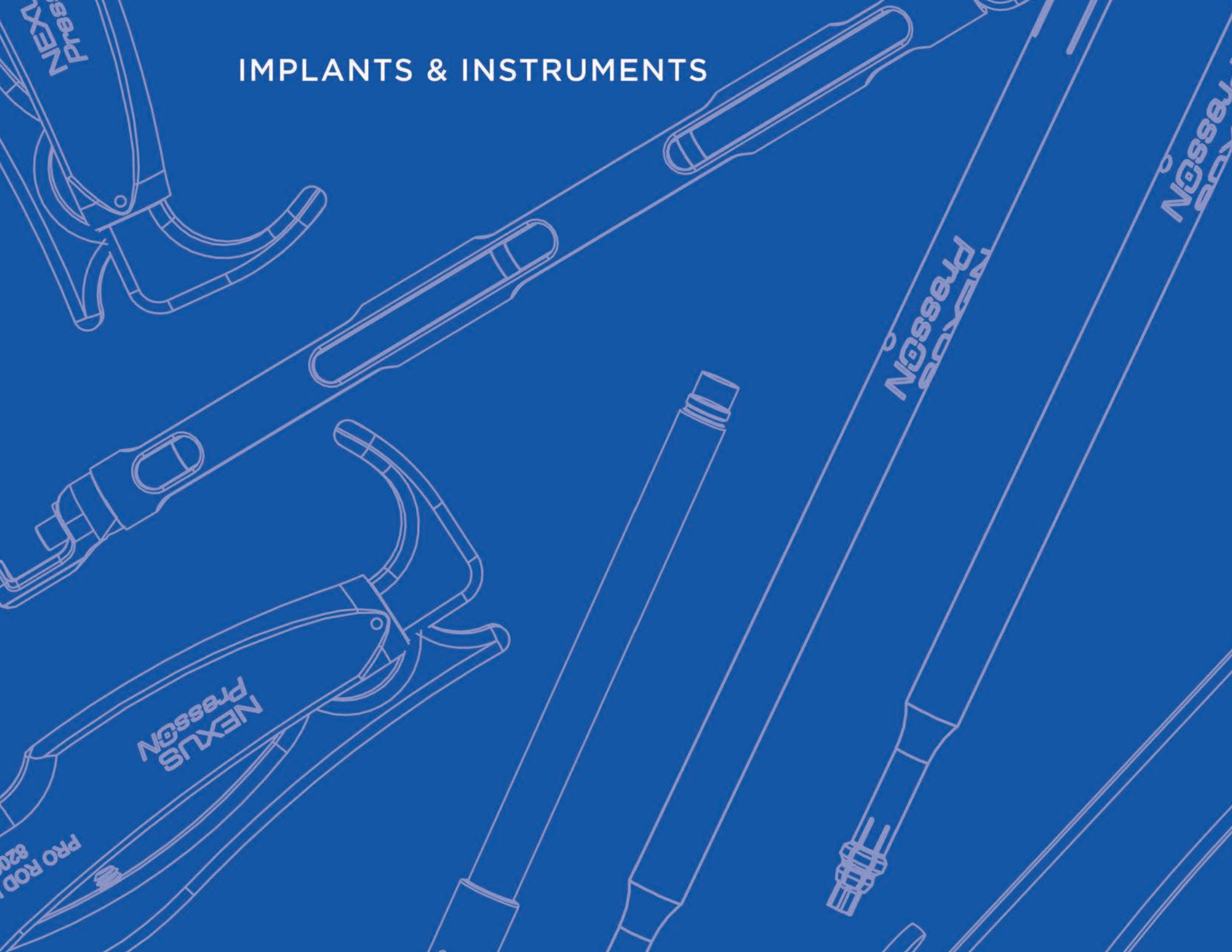
Unlock all Screws. Multi-Level Rods do not need to be unlocked for removal.

Use the External Driver or Internal Retaining Driver to perform Pedicle Screw insertion in reverse by setting the Ratcheting Handle to the “Reverse” (counterclockwise) position.

Note: First remove any soft tissue from within the threaded portion of the screw couplers. A Removal Drill is provided for this purpose.

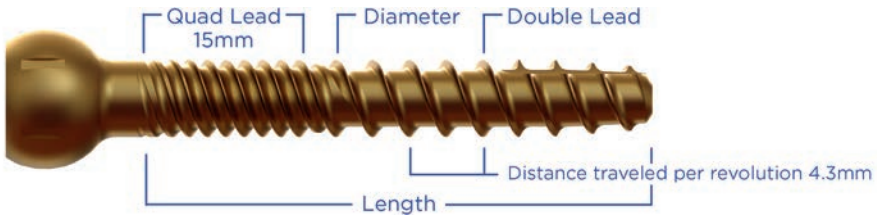

NEXUS PressON
PRO ONE SCREW LOCKER
820051B
XXXX
NEXUS PressON 820137 PRO ROD HOLDER XXXX
NEXUS PressON PISTOL UNLOCKER 820043 XXXX

IMPLANTS & INSTRUMENTS



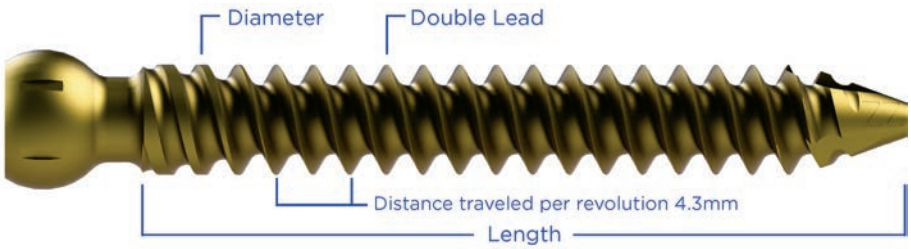
PEDICLE SCREWS

CORTICAL SCREW



LENGTH	DIAMETER	
	4.5mm	5.0mm
25mm	X	X
30mm	X	X
35mm	X	X
40mm	X	X
45mm	X	X
50mm	X	X

CANCELLOUS SCREW



LENGTH	DIAMETER			
	5.5mm	6.5mm	7.5mm	8.5mm
25mm	X	X	X	X
30mm	X	X	X	X
35mm	X	X	X	X
40mm	X	X	X	X
45mm	X	X	X	X
50mm	X	X	X	X
55mm	X	X	X	X
60mm			X	X
65mm				X
70mm				X
75mm				X
80mm				X

FIXED-LENGTH RODS

1-LEVEL FIXED LENGTH ROD

LENGTH

12mm	2mm Increment
14mm	
16mm	
18mm	
20mm	
22mm	
24mm	
26mm	
28mm	
30mm	
32mm	
34mm	
36mm	
39mm	3mm Increment
42mm	
45mm	
48mm	
51mm	
54mm	
57mm	
60mm	
62.5mm	2.5mm Increment
65mm	
67.5mm	
70mm	
72.5mm	
75mm	
77.5mm	
80mm	

2-LEVEL FIXED LENGTH ROD

LENGTH B	LENGTH A										
	12	14	16	18	20	22	24	27	30	33	36
12	12x12	12x14	12x16	12x18	12x20	12x22	12x24	12x27	12x30	12x33	12x36
15		15x14	15x16	15x18	15x20	15x22	15x24	15x27	15x30	15x33	15x36
18			18x16	18x18	18x20	18x22	18x24	18x27	18x30	18x33	18x36
21				21x18	21x20	21x22	21x24	21x27	21x30	21x33	21x36
24					24x20	24x22	24x24	24x27	24x30	24x33	24x36
27						27x22		27x27	27x30	27x33	27x36
30									30x30	30x33	30x36
33										33x33	33x36
36											36x36

MULTI-LEVEL IMPLANTS

DOUBLE COUPLER

LENGTH

- 12mm
- 14mm
- 16mm
- 18mm
- 20mm
- 22mm
- 24mm
- 26mm
- 28mm
- 30mm
- 32mm
- 34mm
- 36mm
- 39mm
- 42mm
- 45mm
- 48mm
- 51mm
- 54mm
- 57mm
- 60mm
- 62.5mm
- 65mm
- 67.5mm
- 70mm
- 72.5mm
- 75mm
- 77.5mm
- 80mm

HYRBRID ROD

LENGTH

- 18mm
- 20mm
- 22mm
- 24mm
- 26mm
- 28mm
- 30mm
- 32mm
- 34mm
- 36mm
- 39mm
- 42mm
- 45mm
- 48mm
- 51mm
- 54mm
- 57mm
- 60mm
- 62.5mm
- 65mm
- 67.5mm
- 70mm
- 72.5mm
- 75mm
- 77.5mm
- 80mm

L-ROD

LENGTH

- 18mm
- 20mm
- 22mm
- 24mm
- 26mm
- 28mm
- 30mm
- 32mm
- 34mm
- 36mm
- 39mm
- 42mm
- 45mm
- 48mm
- 51mm
- 54mm
- 57mm
- 60mm
- 62.5mm
- 65mm
- 67.5mm
- 70mm

ROD

LENGTH

- 24mm
- 26mm
- 28mm
- 30mm
- 32mm
- 34mm
- 36mm
- 39mm
- 42mm
- 45mm
- 48mm
- 51mm
- 54mm
- 57mm
- 60mm
- 62.5mm
- 65mm
- 67.5mm
- 70mm

T-COUPLER

END COUPLER

INSTRUMENT LIST

Part Number	Description
820001	Straight Probe
820002	Curved Probe
820093	Straight Lenke Probe
820092	Curved Lenke Probe
820054	Ratcheting T-Handle
820053	Ratcheting Straight Handle
820122	Ratcheting Palm Handle
820003	Straight Sounder
820004	Curved Sounder
820055	4.5mm Tap
820056	5.5mm Tap
820057	6.5mm Tap
820058	7.5mm Tap
820059	8.5mm Tap
820106	4.0mm Cortical Tap
820107	4.5mm Cortical Tap
820108	5.0mm Cortical Tap
820128	Internal Retaining Driver
820060	Driver
820062	External Driver
820133	Cortical Internal Retaining Driver
820017	Calipers
820116	Construct Builder
820137	Rod Holder
820051X	Screw Locker
820109	Rod Pusher
820026	Rod Locker
820126	Torque Limiting T-Handle
820070	Counter Torque
820131	ML Counter Torque
820069	Screw Unlocker
822040	Fixed T-Handle
820027	Rod Unlocker
820200	Removal Drill

Note: All instruments are 65% actual size.

STRAIGHT PROBE (820001)

CURVED PROBE (820002)

STRAIGHT LENKE PROBE (820093)

CURVED LENKE PROBE (820092)

INSTRUMENT LIST CONTINUED

RATCHETING T-HANDLE (820054)

RATCHETING STRAIGHT HANDLE (820053)

RATCHETING PALM HANDLE (820122)

STRAIGHT SOUNDER (820003)

CURVED SOUNDER (820004)

TAP (820055-820059)

CORTICAL TAP (820106-820108)

INTERNAL RETAINING DRIVER (820128)

DRIVER (820060)

EXTERNAL DRIVER (820062)

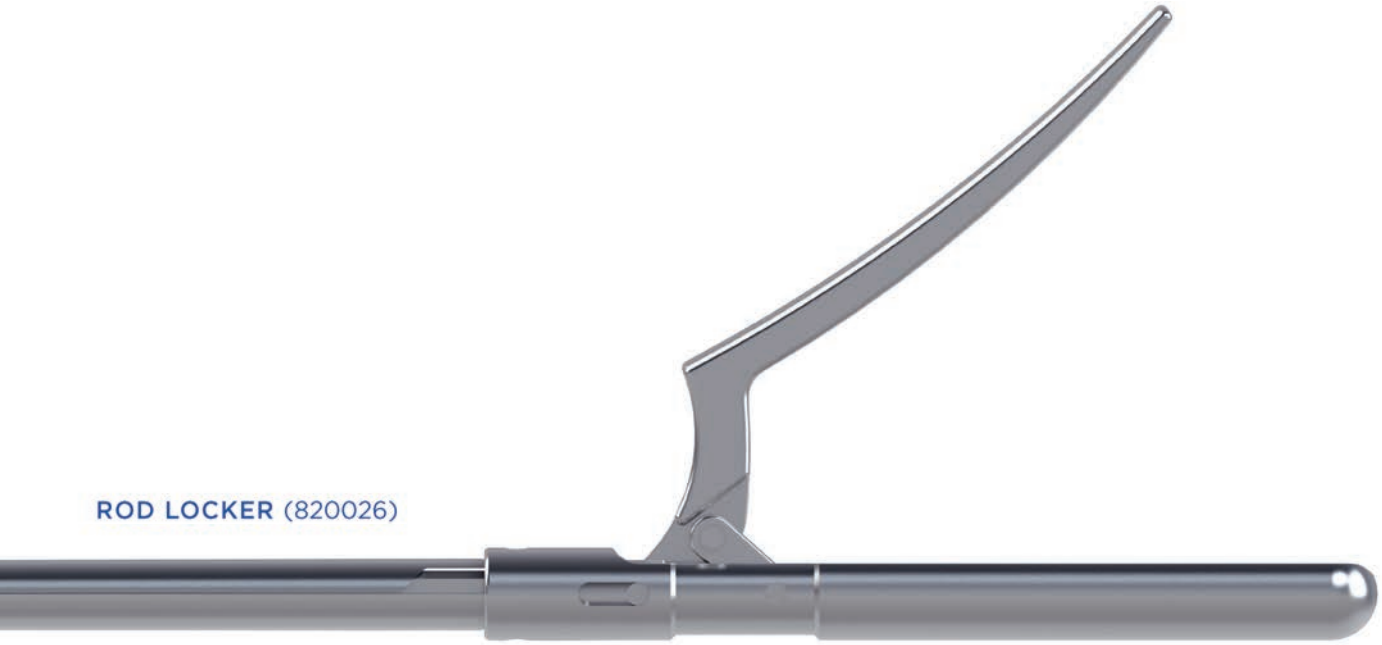
CORTICAL INTERNAL RETAINING DRIVER (820133)

INSTRUMENT LIST CONTINUED

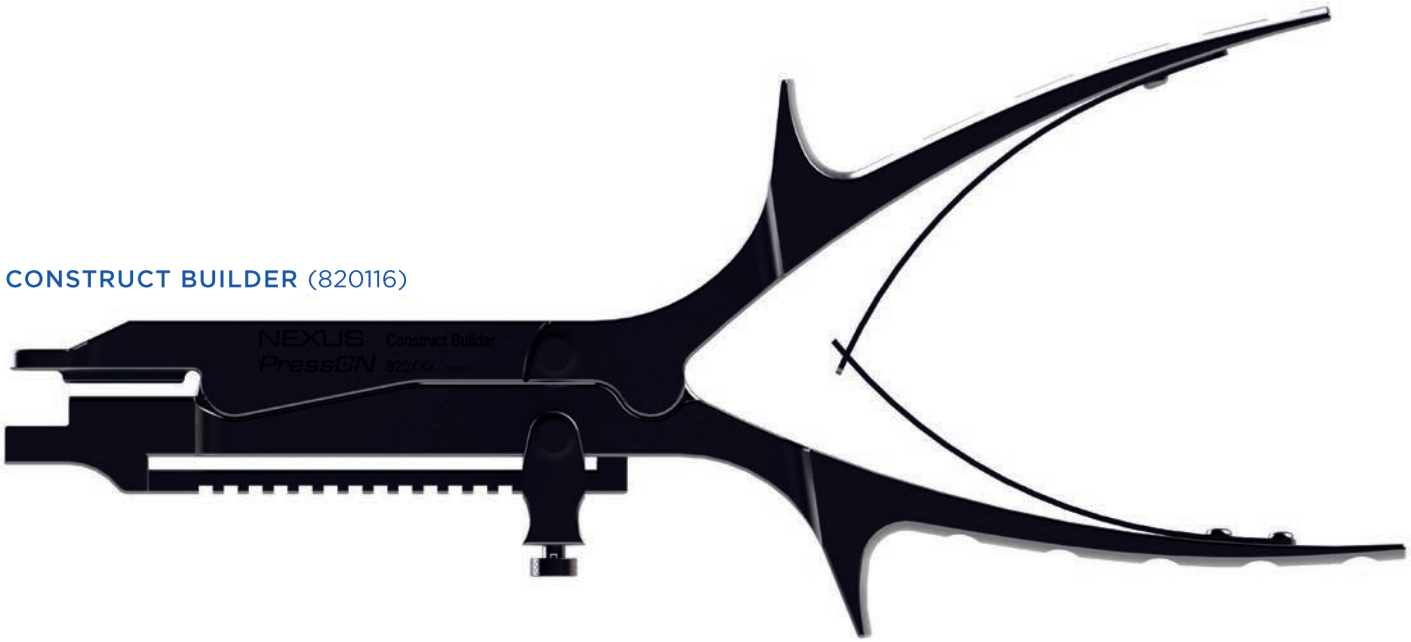
ROD HOLDER (820137)

CALIPERS (820017)

ROD PUSHER (820109)



ROD LOCKER (820026)



CONSTRUCT BUILDER (820116)

SCREW LOCKER (820051X)

INSTRUMENT LIST CONTINUED

REMOVAL DRILL (820200)

SCREW UNLOCKER (820069)

ML COUNTER TORQUE (820131)

COUNTER TORQUE (820070)

TORQUE LIMITING T-HANDLE (820126)

FIXED T-HANDLE (822040)

ROD UNLOCKER (820027)

DESCRIPTION

The PressON™ Spinal Fixation System is composed of the following:

Pedicle Screws
Rods
Couplers
Transverse Connectors

These components can be assembled and implanted using associated instruments via a posterior approach into the pedicles of the non-cervical vertebral bodies. Components are made from Ti-6Al-4V ELI (ASTM F-136).

INDICATIONS

The PressON Spinal Fixation System is a posterior, non-cervical pedicle screw system intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, fracture, dislocation, scoliosis, kyphosis, lordosis, spinal tumor, and failed previous fusion (pseudarthrosis).

CONTRAINDICATIONS

Contraindications include, but are not limited to:

- Infection
- Morbid obesity
- Mental illness
- Fever or leukocytosis
- Pregnancy
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis
- Cardiovascular complications
- Allergic or other reaction to the metallic implants
- Inadequate tissue coverage over operative site
- Any case not needing a fusion
- Any patient unwilling to cooperate with the postoperative instructions

POTENTIAL ADVERSE EFFECTS

All patients considered candidates for fusion using the pedicle screw system should be informed concerning the pathogenesis of their spinal abnormality, the rationale for fusion with instrumentation, and the potential adverse effects associated with the procedure. The potential adverse effects include, but are not limited to:

- Bending, disassembly, loosening, fracture, slippage, and/or migration of the components
- Foreign body reaction to the implants
- Skin or muscle sensitivity
- Non-union or delayed union
- Infection
- Loss of proper spinal curvature, correction, height, and/or reduction
- Loss of neurological function, dural tear, pain, and/or discomfort
- Epidural bleeding, hemorrhage of blood vessels, and/or hematomas
- Loss of bladder and/or bowel control
- Sterility, impotency, and/or loss of consortium
- Bone loss and/or bone fracture due to stress shielding
- Bursitis
- Bone graft donor site pain
- Cardiovascular disorders including venous thrombosis, pulmonary embolism, cerebrovascular accident, and /or myocardial infarction
- Death

WARNINGS AND PRECAUTIONS

Warning: This device is not intended for attachment to the cervical spine.

Warning: 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 neurological 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.

Precaution: 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.

The components of this system should not be used with components of any other systems or manufacturers.

Preoperative and operating procedures, including knowledge of surgical techniques and proper selection and placement of the implants, are essential considerations in the utilization of this device.

Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may affect the performance of the system.

Patient selection and compliance will greatly affect the results. Patients suffering from obesity, malnutrition, and/or poor bone quality are poor candidates for spinal fusion. Patients who smoke or abuse alcohol are poor candidates for spinal fusion.

A successful result is not always achieved in every surgical case due to many extenuating circumstances. This device is intended for temporary immobilization of the non-cervical spine in order to obtain a solid fusion mass using a bone graft. The durability and success of the implant will be compromised in cases where a non-union develops, or when used without a bone graft.

The screws of this device are not intended for insertion into the pedicles to facilitate cervical spinal fusion.

The benefit of spinal fusion utilizing any pedicle screw system has not been adequately established in patients with stable spines.

Potential risks identified with the use of the device system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebrae, neurological injury, and/or vascular or visceral injury.

PREOPERATIVE

Patients who meet the criteria in Indications should be considered for surgery. Patient conditions such as those addressed in Contraindications should be avoided. The surgeon should confirm that all implants and instruments are unpacked, sterilized, and available prior to surgery. Implants and instruments should be inspected for surface flaws and scratches and should not be used in the presence thereof.

INTRAOPERATIVE

The surgical technique manual should be followed. Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions. Mishandling of instruments may cause injury to patient and/or operative personnel. Bone grafts should be used to ensure stability. Notching and scratching of implants should be avoided. All implants are to be tightened firmly and rechecked before closing soft tissue.

POSTOPERATIVE

For best possible results, patients should be counseled to avoid lifting, twisting, physical activities, smoking, consuming alcohol, and any other activity that would compromise or delay the healing process. The patient should be warned about the limitation of bending at the point of spinal fusion. After the spinal fusion is complete, the surgeon must consider removing the implant, as this device serves no functional purpose after complete spinal fusion. If the device is not removed, the following complications may occur: implant corrosion, migration, bending, breaking and/or loosening, infection, bone loss, pain, and/or soft tissue reaction.

CLEANING AND DECONTAMINATION

Clean and sanitize implants and instruments in a neutral pH enzymatic detergent solution before sterilization and introduction into a surgical field or return of the product to Nexus™. Use manual cleaning with a soft bristled brush and blunt needle syringes (for irrigation of cannula or other cavities) to remove gross soil and debris. Follow manual cleaning with ultrasonic cleaning in a bath of neutral pH enzymatic detergent solution to remove remaining soil and debris. After ultrasonic cleaning, thoroughly rinse with deionized water. Dry implants and instruments thoroughly before placing in trays for sterilization. Visually inspect all the instruments for evidence of organic material. Repeat the ultrasonic clean and rinse step if needed. Any implant that has not been used but has become soiled, should be handled according to hospital protocol. NEXUS™ does not recommend reprocessing of soiled implants.

PACKAGING AND STERILITY

PressON™ Spinal Fixation System Implants are supplied as non-sterile single use implants. All the implants and instruments must be sterilized prior to use. Remove all packaging before sterilization. Sterilization trays must be double wrapped using a 510(k) approved single use, single-ply sterilization wrap with a weight limit of at least 25 lbs prior to each sterilization. The recommended sterilization process is pre-vacuum steam autoclave at 132°C minimum, with a cycle time of 4 minutes, and a minimum dry time of 30 minutes. This process has been validated to a Sterility Assurance Level (SAL) of 10^{-6}. The testing was performed per ISO-17665:1 Sterilization of Health Care Products--Moist Heat--Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices.

PRODUCT HANDLING

Implants should be used only if received with packaging and labeling intact. Protect the implants from contact with objects that may damage the surface finish. Inspect each implant prior to use for visual damage. Damaged packaging and implants should not be used and should be returned to NEXUS™.

PRODUCT COMPLAINTS

Any complaint or dissatisfaction with product quality, performance, labeling, and/or safety should be reported to NEXUS™. If any of the implants or instruments "malfunction" (i.e. do not meet any of their performance specifications or do not perform as intended), and/or are suspected to have caused or contributed to the death or serious injury of the patient, NEXUS™ should be notified immediately by phone, fax or written correspondence.

When filing a complaint, please provide the product description, product number, lot number, complainant's name and address, and the nature of the complaint.

CAUTION

Federal Law (USA) restricts this device to sale, distribution, and use by or on the order of a physician.

LIT-4034 PressON IFU Rev B

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SPINE

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LIT-4086 Rev A