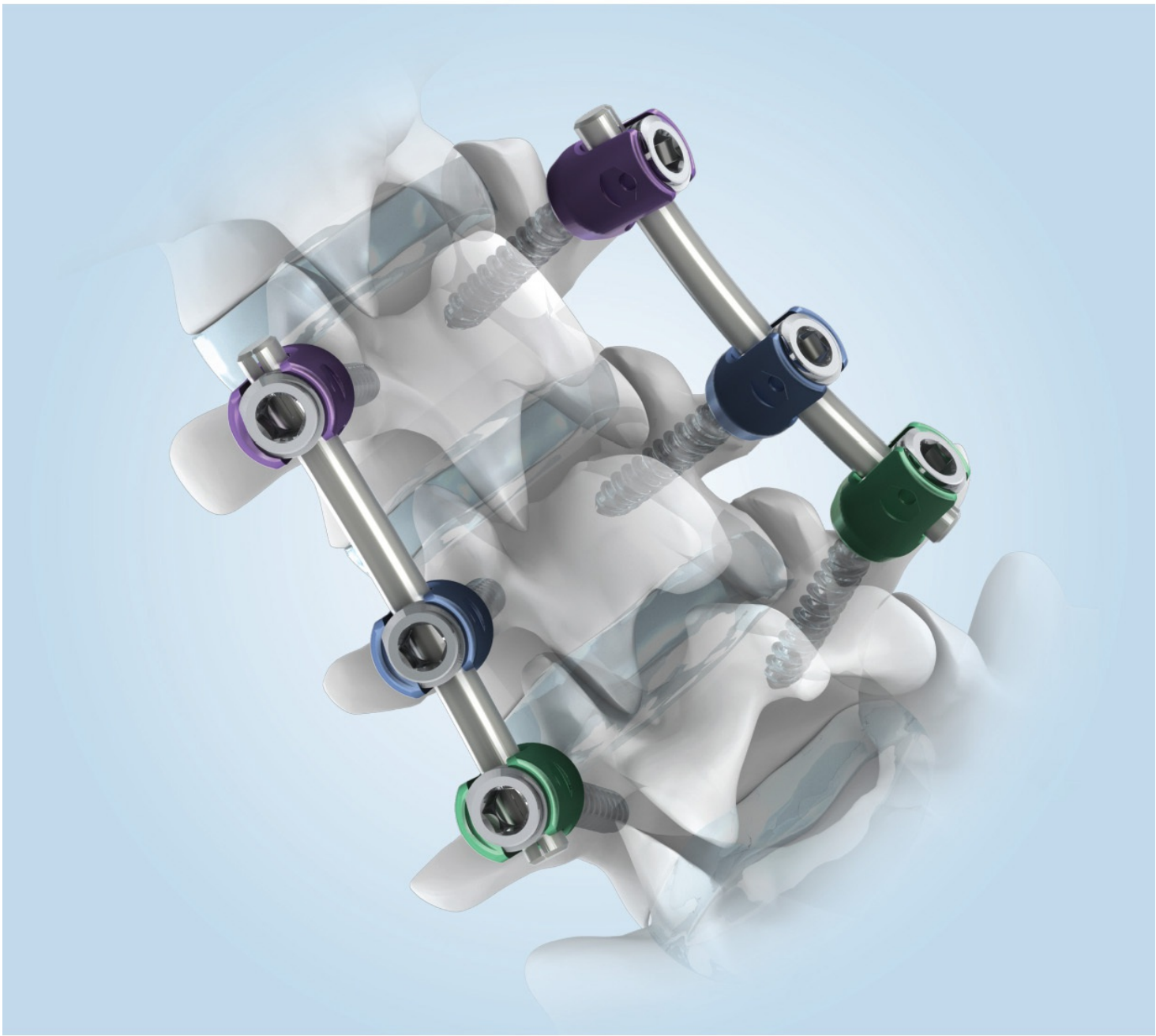
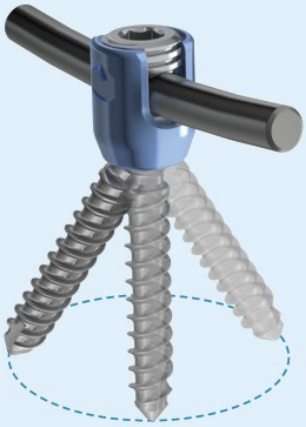
ANAX™ 5.5 Spinal System

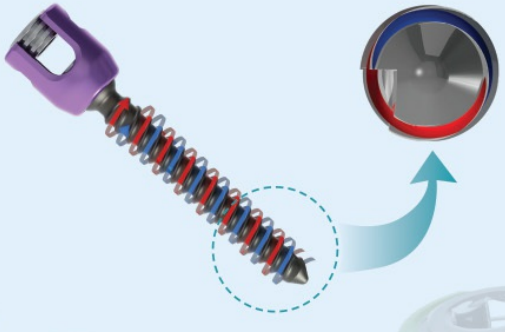
Surgical Technique



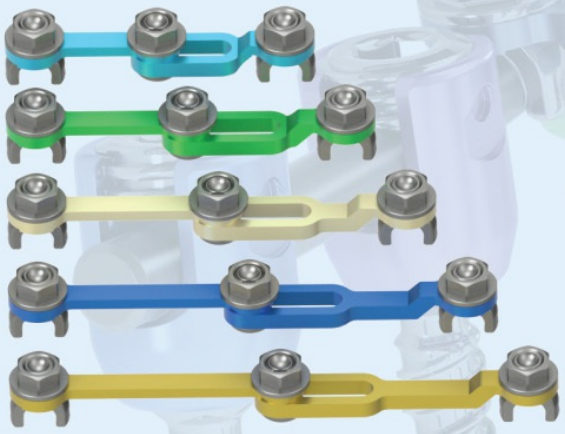
U&I CORPORATION



Allowable angulation of screw
up to 65° in all directions

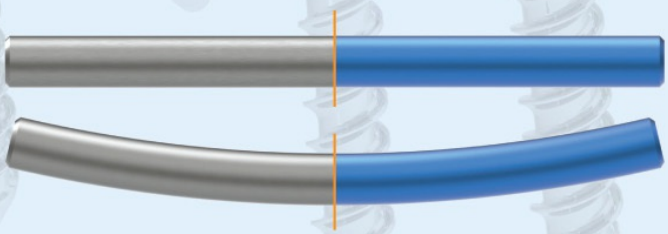


Double helical screw thread
accelerates insertion without compromising screw purchase and reduce surgeon fatigue



Color coded top-loading type of cross link

Straight and curved Ø5.5mm
Titanium (Ti)
and Cobalt-Chrome (CoCr) rods



SITE PREPARATION

Instrument	
SG0001	AWL
SF0280	STRAIGHT PROBE
SF0290	CURVED PROBE
SF0300	TESTER - STRAIGHT
SF0310	TESTER - CURVED

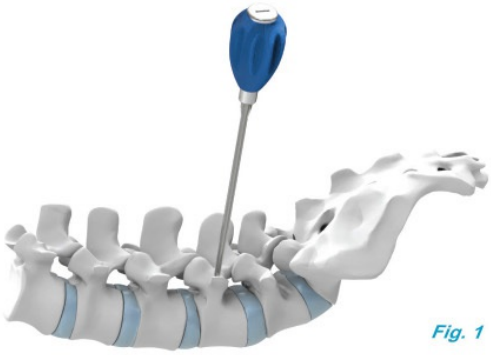


Fig. 1

Identify the correct anatomical landmarks for creating an entry point for the pedicle screw pilot hole.
Drawing a horizontal line through the middle of the transverse process and a vertical line through the superior facet of the vertebral level being addressed will give you an approximate entry point to the pedicle.
Once the entry point is identified, the AWL is used to penetrate the cortical bone and create a pilot hole (Fig.1).

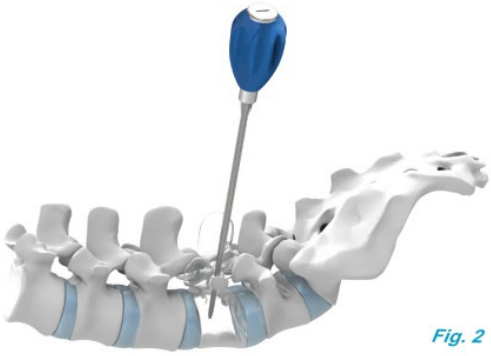


Fig. 2

Determine the pedicle canal entry site. Insert the PROBE into the established entry site, gently pressing through the pedicle canal to determine hole depth (Fig.2). It is important that the appropriate cephalad/caudad and converging angles are observed when engaging the PROBE.

Apply slight downward pressure while rotating back and forth to advance the PROBE into the pedicle and down into the anterior column.

Insert the TESTER to palpate the hole's inner surface to verify pedicle wall integrity (Fig.3).

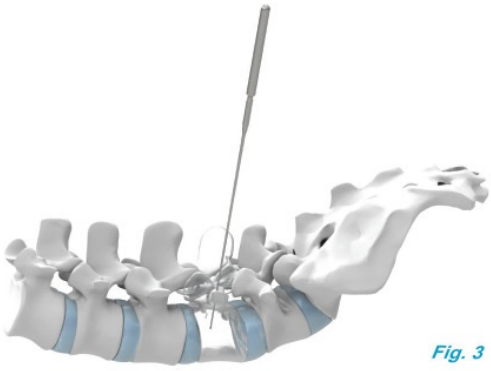


Fig. 3

(OPTIONAL) GUIDE PIN

Optional Instrument	
SF0240	GUIDE PIN - LEFT
SF0250	GUIDE PIN - RIGHT

The GUIDE PIN may be placed to identify appropriate screw trajectory via a lateral X-ray/fluoroscopy view (Fig.4).

Fig. 4

TAP

Instrument	
SF0040 ~ SF0080	TAP, Ø 4.0mm ~ Ø 8.0mm
SP0040	FD RATCHET HANDLE

Polyaxial/Monoaxial screws are fully threaded and have a self-tapping feature designed to eliminate the need to tap the pedicle canal.

In many situations where patient bone quality is compromised or where there is a dense cortical layer, it may be necessary to utilize one of the size-specific taps in the ANAX™ 5.5 Spinal System.

Taps are undersized to ensure a press fit with the pedicle screw. It is not necessary to undersize the TAP based on choice of screw diameter.

Choose the appropriate diameter TAP based on the diameter of screw to be implanted.

Attach the TAP to the FD RATCHET HANDLE. Shift handle into the forward position and advance clockwise into the pedicle canal. Laser marked lines on the tap begin at 30mm and continue in increments of 10mm.

Advance to desired depth, shift the ratcheting handle in reverse, and remove the tap in counter-clockwise direction (Fig.5).

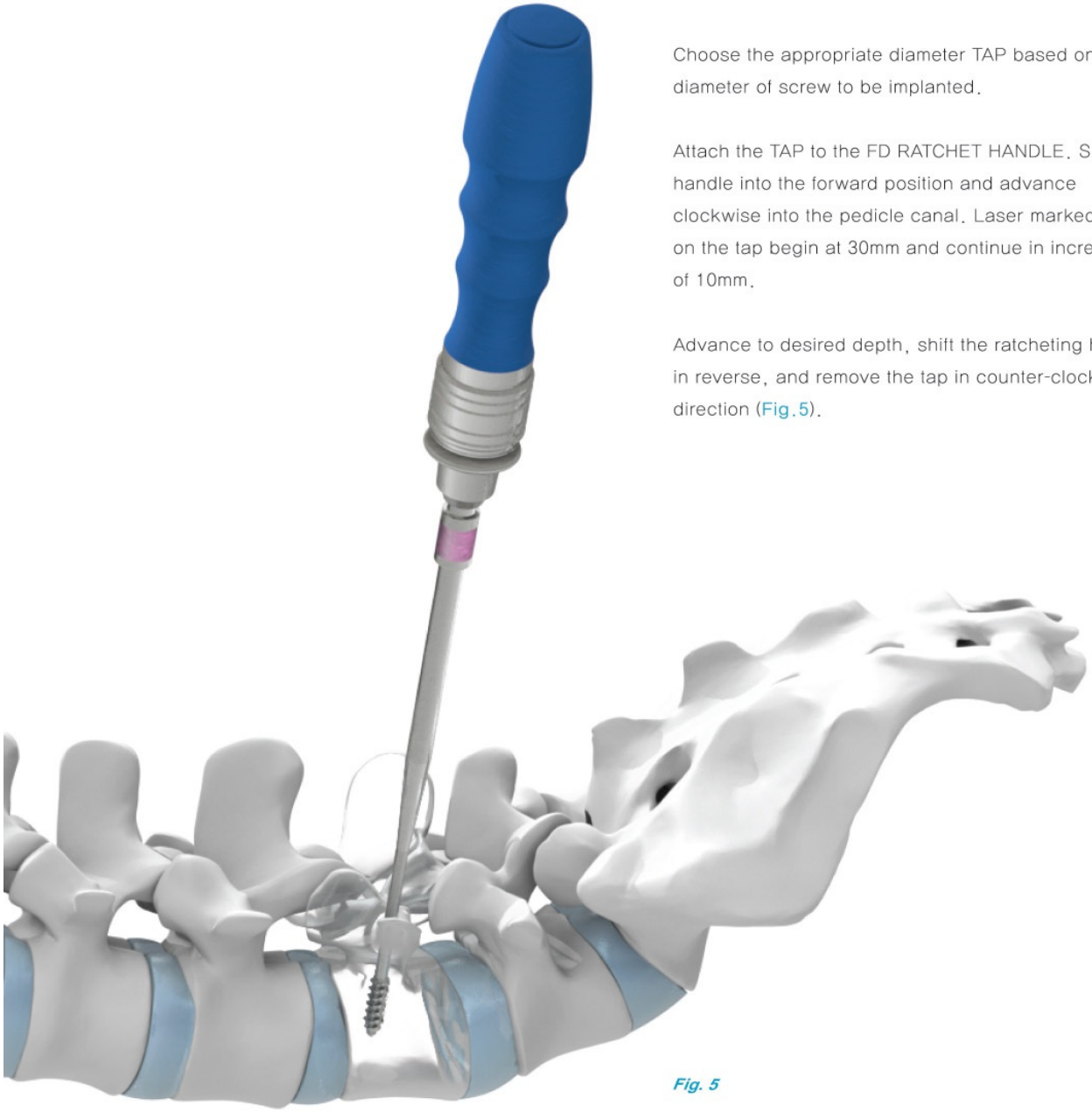


Fig. 5

SCREW INSERTION

Instrument	
SF0010	POLYSCREW DRIVER
SF0020	MONOSCREW DRIVER
SP0040	FD RATCHET HANDLE

Insert the hex end of the driver into the hex feature on the center of the pedicle screw shank. Confirm that the shank of the screw is straight ❶. Advance the sleeve into the threads in the head of screw until tight ❷.

Once secured, advance the locker to the knob ❸. Attach the FD RATCHET HANDLE to the SCREW DRIVER ❹.

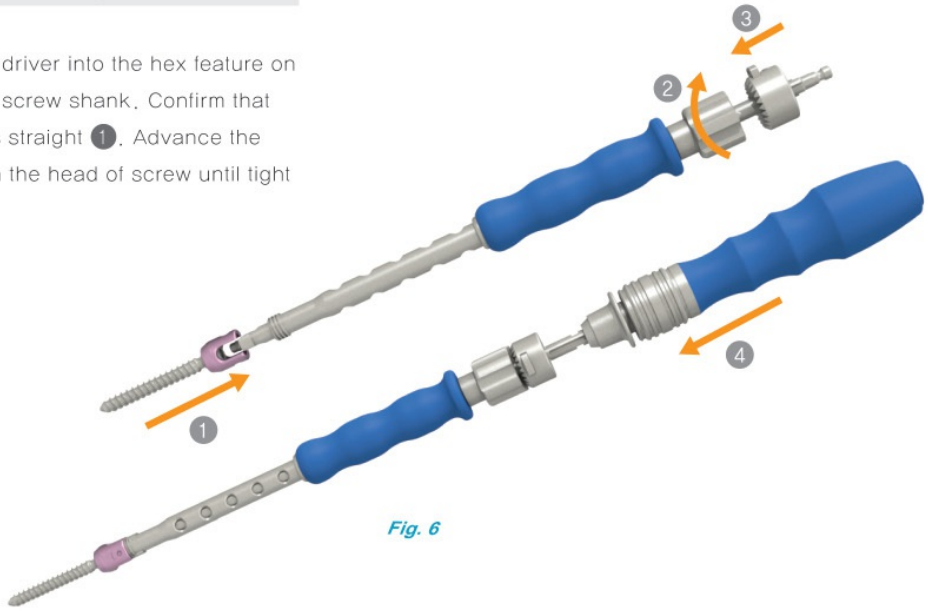
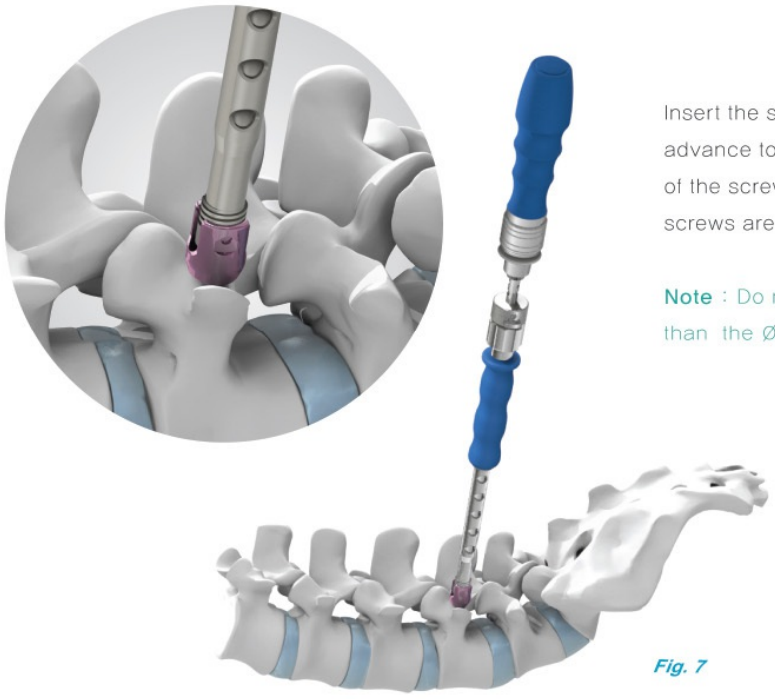


Fig. 6



Insert the screw into the prepared pedicle and advance to a depth where full angulation of the head of the screw is maintained. Repeat process until all screws are placed (Fig.7).

Note : Do not use a screw that is smaller diameter than the Ø7.0mm screw for the sacrum

Fig. 7

(OPTIONAL) SCREW INSERTION DEPTH

Instrument	
SN0042	SCREW ADJUSTMENT INSTRUMENT

The SCREW ADJUSTMENT INSTRUMENT can be used to adjust the screw height (Fig.8).

Note : Do not insert polyaxial screw via the SCREW ADJUSTMENT INSTRUMENT.

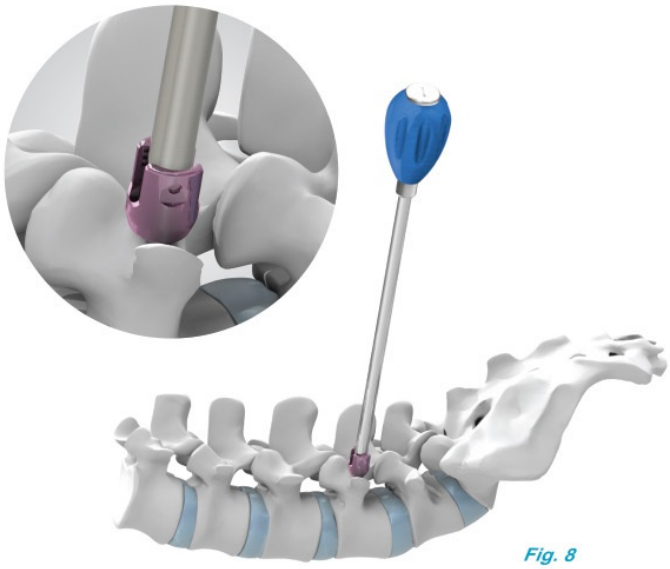


Fig. 8

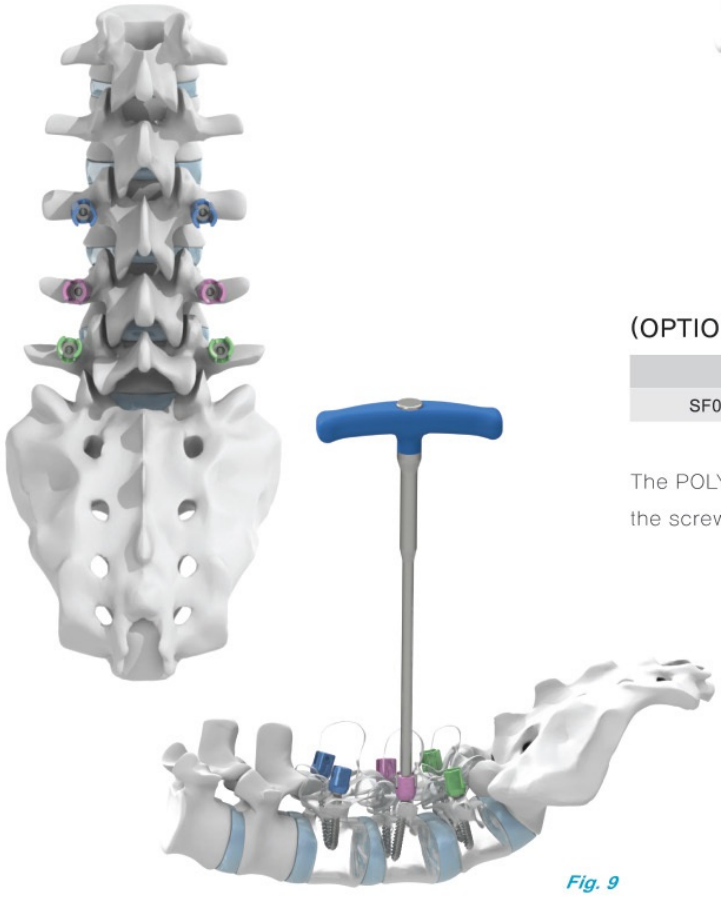


Fig. 9

(OPTIONAL) SCREW HEAD ALIGNMENT

SF0150	POLY HEAD ADJUSTER

The POLY HEAD ADJUSTER can be utilized to align all the screw heads (Fig.9).

ROD PREPARATION

Instrument	
SF0100	ROD BENDER

The ANAX™ 5.5 Spinal System offers a wide range of pre-cut and pre-contoured 5.5mm rods.

Once the screws have been placed, appropriate rod length is determined. It is recommended that 3~5mm of the rods extend beyond the head of the screw on the superior and inferior ends of the construct.

Rod bending is sometimes necessary to ensure that the rod is fully seated within the head of the screw.

The ROD BENDER is used to contour the rods. The angle of bend can be varied by adjusting the central button on the rod bender. The various angles may be selected by pulling out on the central button on the ROD BENDER while adjusting the central button as desired (Fig.10).

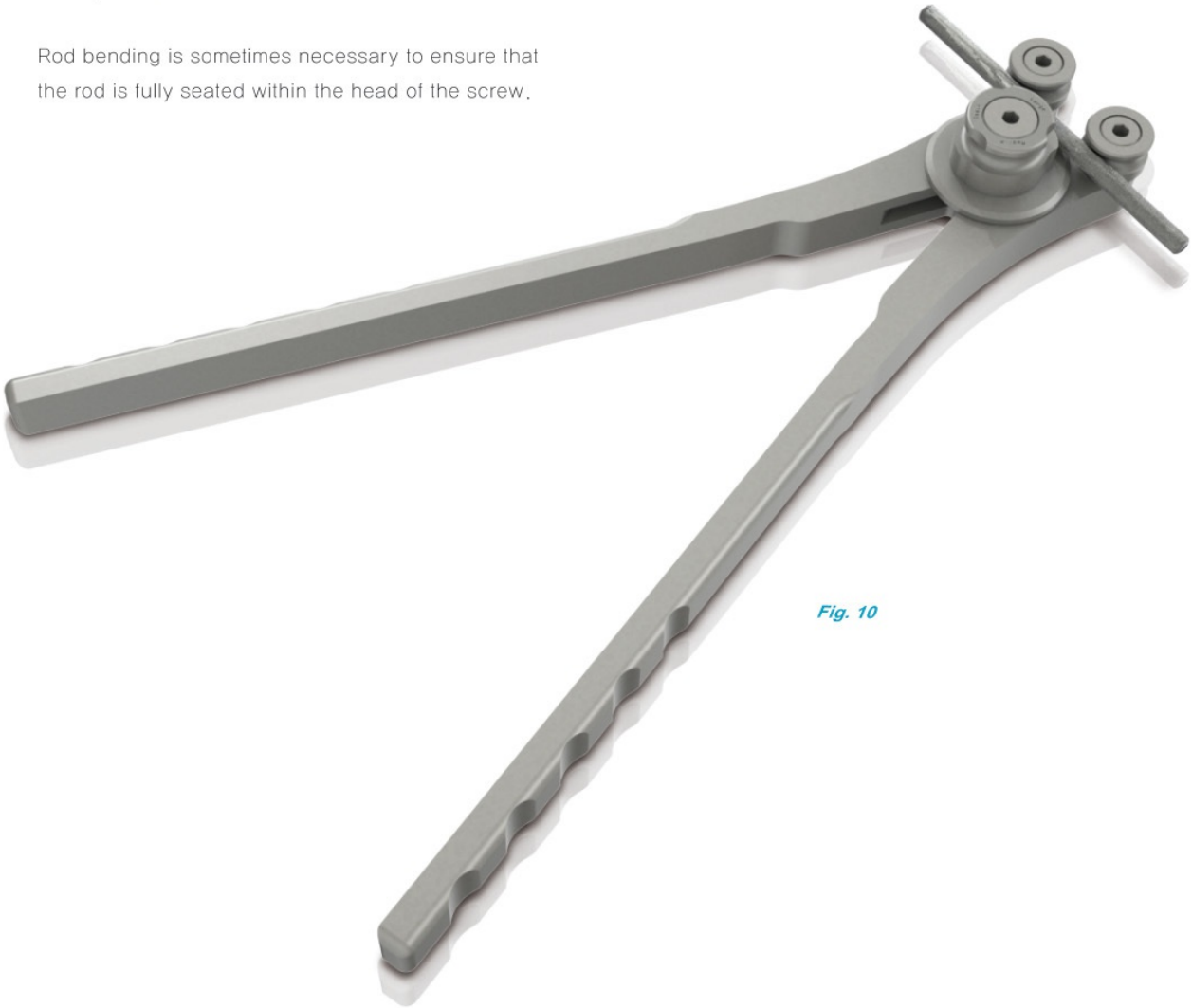


Fig. 10

ROD INSERTION

Instrument	
SF0090	ROD HOLDER

Once the desired rod length is chosen and the contouring is complete, the rod can be placed in the screw heads.

The ROD HOLDER is used to insert the rod into the heads of the screw (Fig.11).

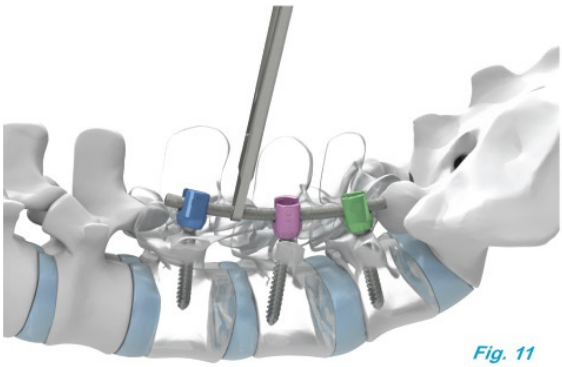


Fig. 11

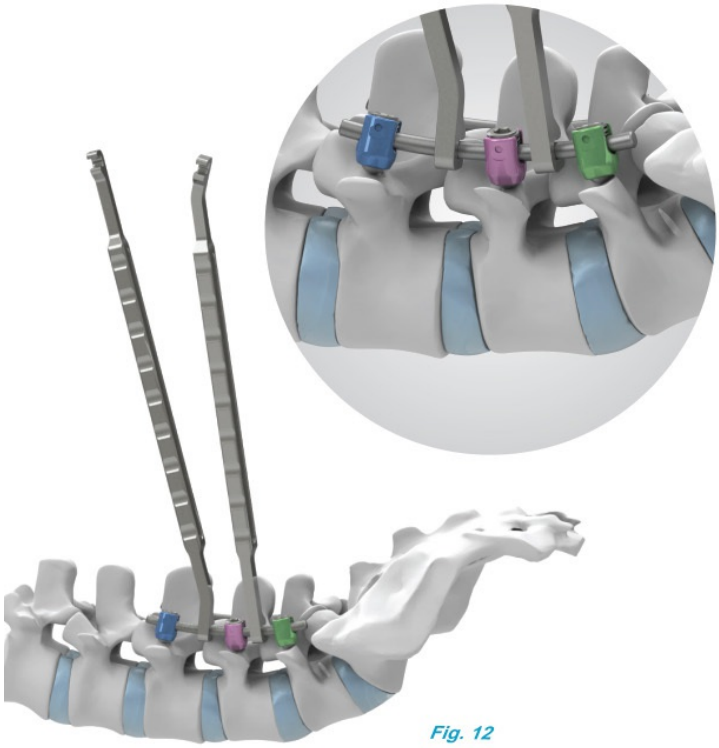


Fig. 12

(OPTIONAL) IN-SITU BEND

Instrument	
SF0170	IN-SITU ROD BENDER - RIGHT
SF0180	IN-SITU ROD BENDER - LEFT

Should further contouring be desired after the Rod is inserted, IN-SITU ROD BENDERs are available.

The paired IN-SITU ROD BENDER (LEFT/RIGHT) are constructed to receive the rod at 70° one end and 90° on the other. These instruments address lordotic and kyphotic in-situ bending procedures (Fig.12).

(OPTIONAL)
ROD INTRODUCTION

Option 1 - ROD PUSHER

Instrument	
SF0270	ROD PUSHER

To push the rod, place the ROD PUSHER on the rod and apply controlled downward pressure until rod is seated within the screw head (Fig.13).

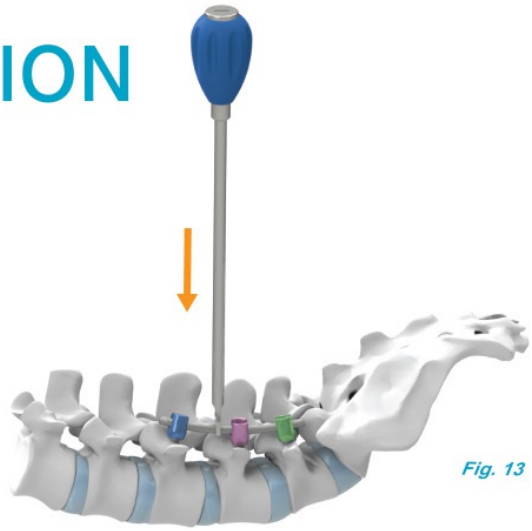


Fig. 13

Option 2 - ROCKER

Instrument	
SF0220	ROCKER

Attach the ROCKER to the round recesses in the sides of the screw head (Fig.14).

Clamp down the ROCKER onto the sides of the screw and then lever backwards over the rod. The levering action allows the rod to be fully seated into screw head.

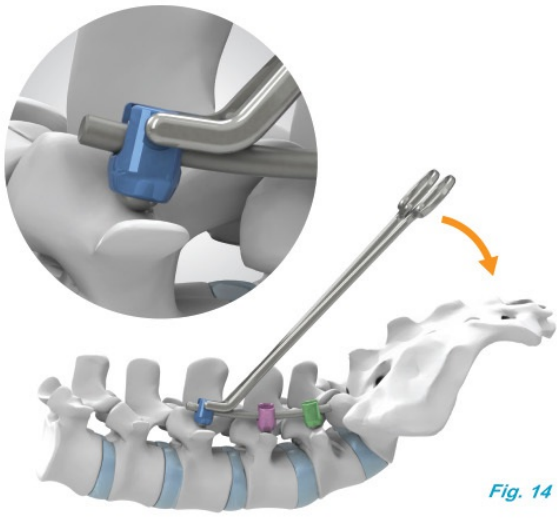


Fig. 14

Option 3 - PERSUADER

Instrument	
SF0130	PERSUADER

Attach the PERSUADER to the round recesses in the sides of the screw head (Fig.15).

Pull the PERSUADER grips to introduce the rod into the screw head.

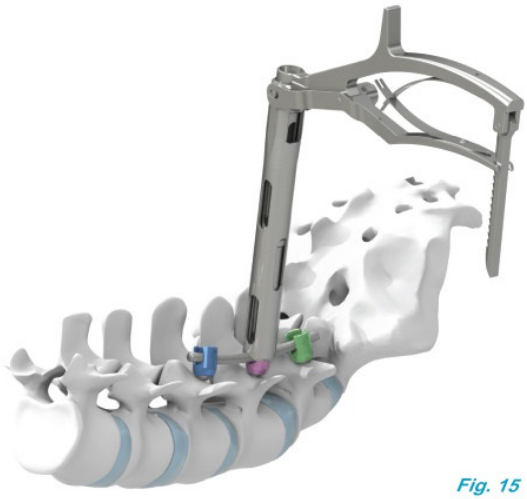


Fig. 15

SET SCREW INSERTION

Instrument	
SF0160	SET SCREW DRIVER GUIDE
SN0009	HOUSING HOLDER

Attach the SET SCREW DRIVER GUIDE to the set screw for the set screw insertion (Fig.16).

Note : Do not final-tighten the set screw via the SET SCREW DRIVER GUIDE.

Note : Verify the proper engagement between the set screw and the housing.

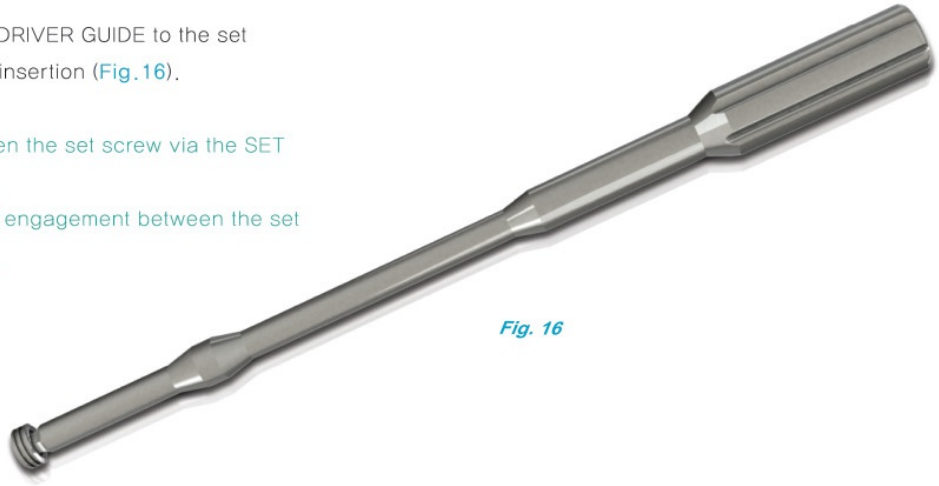


Fig. 16

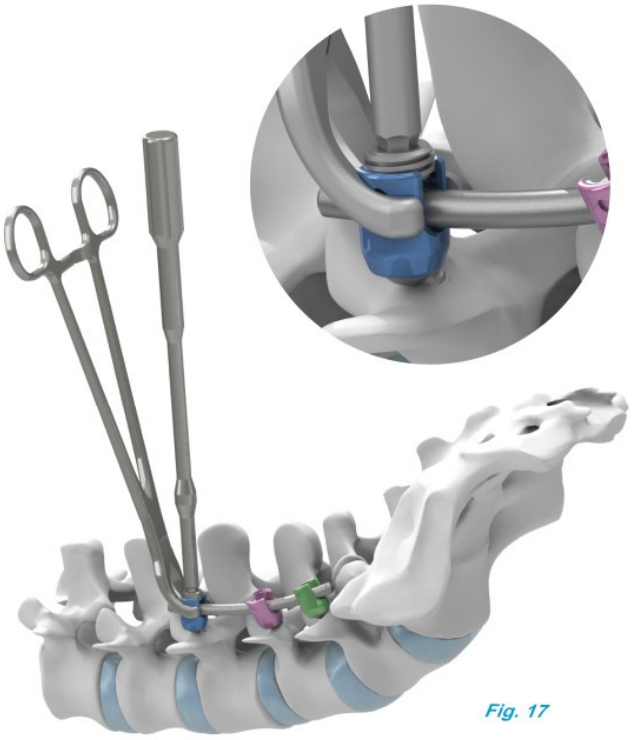


Fig. 17

The HOUSING HOLDER is used to stabilize the housing while inserting the set screw (Fig.17).

Note : Do not use the SET SCREW DRIVER GUIDE with the ANTI-TORQUE DEVICE.

COMPRESSION DISTRACTION, DEROTATION

Instrument	
SF0190	COMPRESSOR for 5.5mm ROD
SF0200	SPREADER for 5.5mm ROD
SF0210	DEROTATOR

Provisionally tighten the set screw on the side of the segment being translated, while leaving the set screw loose on the implant to be compressed or distracted.

Perform compression or distraction against the provisionally tightened assembly with the COMPRESSOR (Fig.18) or SPREADER (Fig.19), respectively.

Ensure that the feet of either the COMPRESSOR or SPREADER are placed firmly against the base of the screw head and not against the tabs, especially for reduction screws.

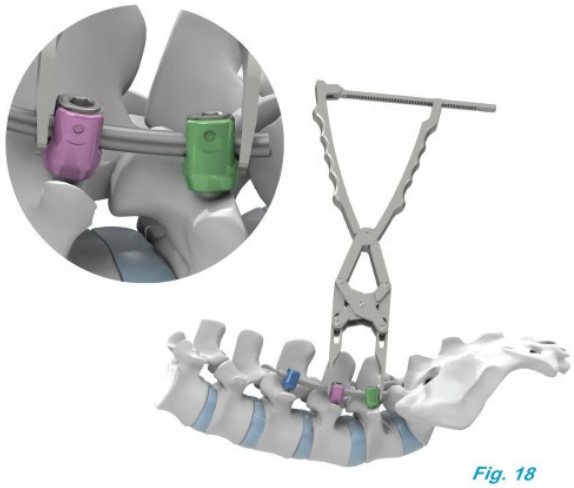


Fig. 18

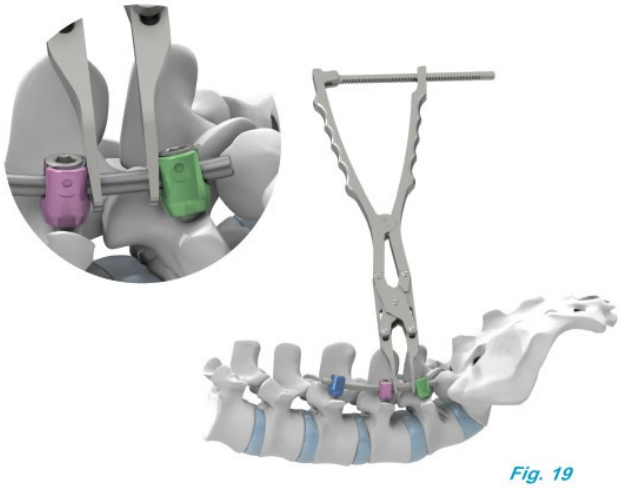


Fig. 19

The DEROATOR is used to rotate the contoured rod into lordosis. The proper position of the rod is confirmed by ensuring that the centerline laser-marked on the rod is visible from the top and parallel to the floor (Fig.20).

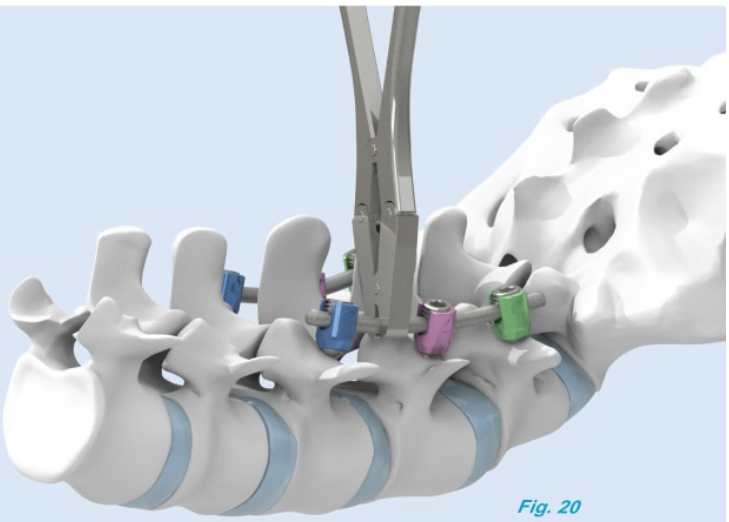


Fig. 20

FINAL TIGHTENING

Once all correction procedures have been completed the construct is ready for final tightening.

Option 1 - AXIAL TORQUE WRENCH

Instrument	
SF0120	AXIAL TORQUE WRNECH 5 HEX (10N-m)
SF0030	ANTI-TORQUE DEVICE

The AXIAL TORQUE WRENCH is inserted into the cannulated hole of the ANTI-TORQUE DEVICE and engaged into the set screw (Fig.21).

Note : Verify the engagement between the 5.0mm hex and the set screw hex.

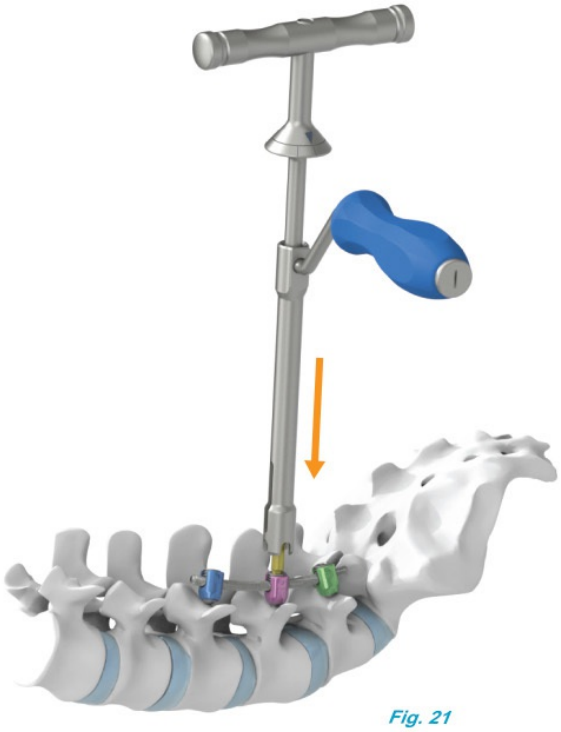


Fig. 21

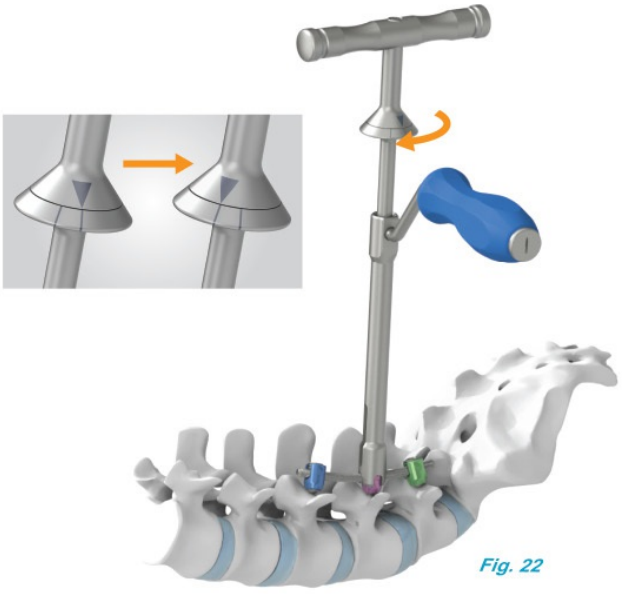


Fig. 22

Lower the ANTI-TORQUE DEVICE over the set screw and rod (Fig.22).

Tighten the set screw until the final tightening position.

Note : Do not tighten the AXIAL TORQUE WRENCH out of vertical.

Option 2 - TORQUE LIMITING T-HANDLE

Instrument	
SF0110	TORQUE LIMITING T-HANDLE (10N-m)
SF0230	5.0mm DRIVER WITH ADAPTOR
SF0030	ANTI-TORQUE DEVICE

Assemble the 5.0mm DRIVER WITH ADAPTOR and TORQUE LIMITING T-HANDLE (Fig.23).

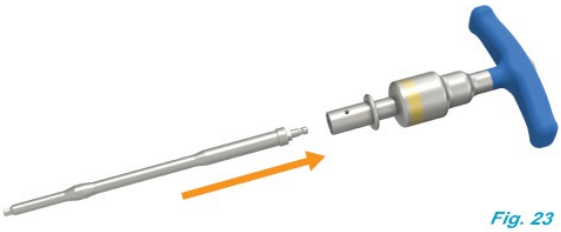


Fig. 23

The 5.0mm DRIVER WITH ADAPTOR is inserted into the cannulated hole of the ANTI-TORQUE DEVICE and engaged into the set screw (Fig.24).

Note : Verify the engagement between the 5.0mm hex and the set screw hex.

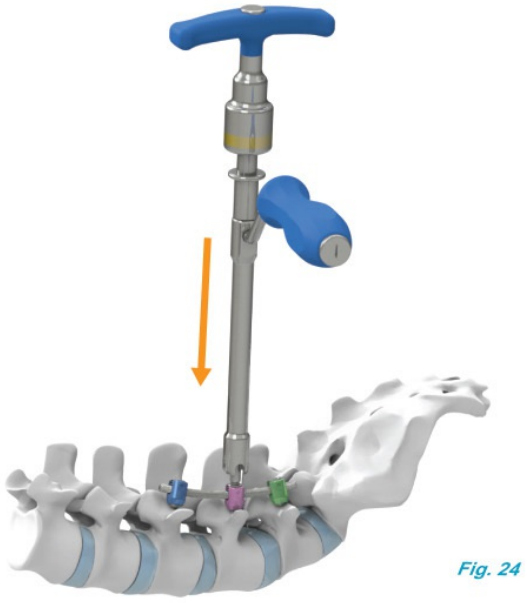


Fig. 24

Begin turning the TORQUE LIMITING T-HANDLE to tighten the set screw (**Fig.25**).

The TORQUE LIMITING T-HANDLE is pre-set to approximately 88.5in-lb (10N-m) and will 'click' once the proper torque is achieved. Repeat tightening of the set screw two or three times per each set screw.

Note : Do not tighten the 5.0mm DRIVER WITH ADAPTOR out of vertical.

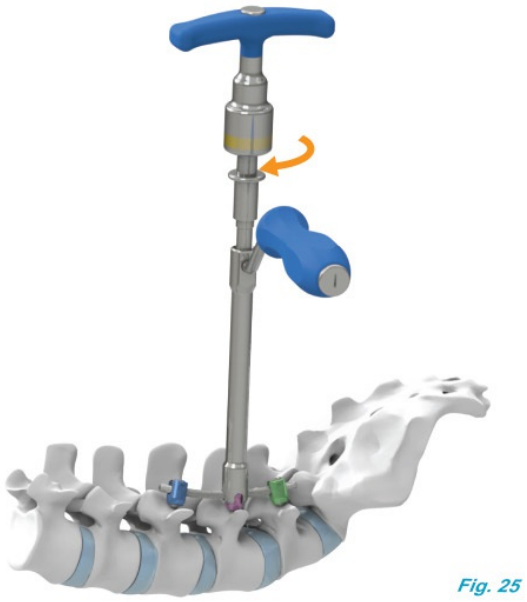


Fig. 25

REDUCTION SCREW

Instrument	
SF0140	ANAX REDUCTION HOUSING CUTTER

When the reduction screws are used, the tabs are broken off when reduction is complete. A snap line allows a clean and easy break.

Grip the one side of the tabs using the ANAX REDUCTION HOUSING CUTTER and bend it in a back and forth motion to break off the tab ❶ (Fig.26). Break off the other side tab in the same manner.

Note : To release the broken tab from the CUTTER, press the button in handle ❷.

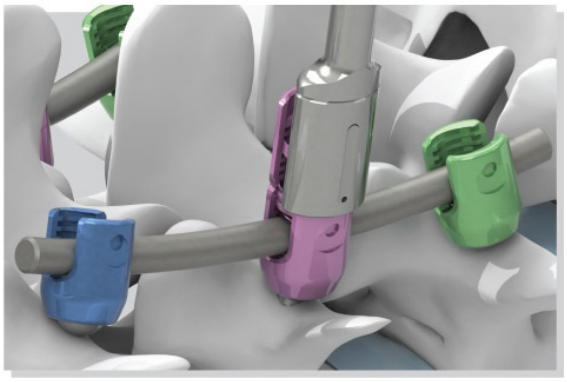


Fig. 26

Crosslink

Instrument	
SF0260	T-LINK HOLDER
SG0032	TORQUE WRENCH for T-LINK COLLET TYPE

Selected Crosslink is held by the T-LINK HOLDER on the Plate A (the narrow plate) to place to desired position.

Note : The T-LINK HOLDER can hold the Plate A ONLY. (Fig.27).

Fig. 27

Both collets of the Crosslink are inserted into the rod by pushing the nut with the TORQUE WRENCH FOR T-LINK COLLET TYPE (Fig.28).

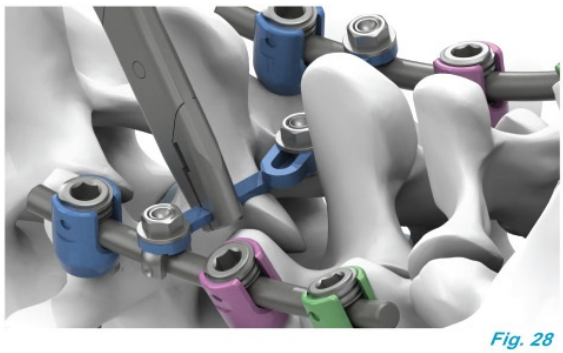
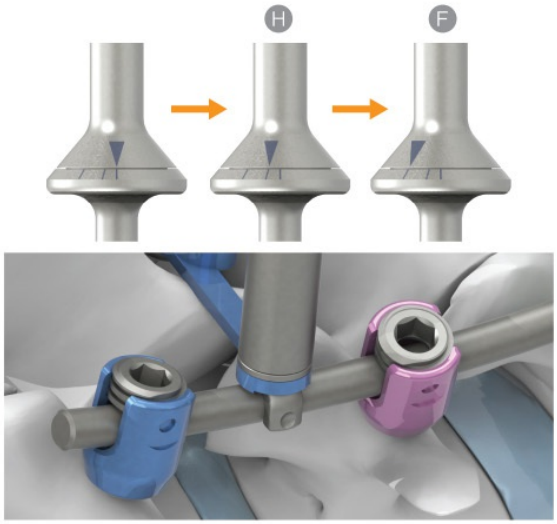


Fig. 28

Use the TORQUE WRENCH FOR COLLET T-LINK COLLET TYPE to tighten the side nut until half torque position (H) and tighten every nut until final torque position (F) (Fig.29).



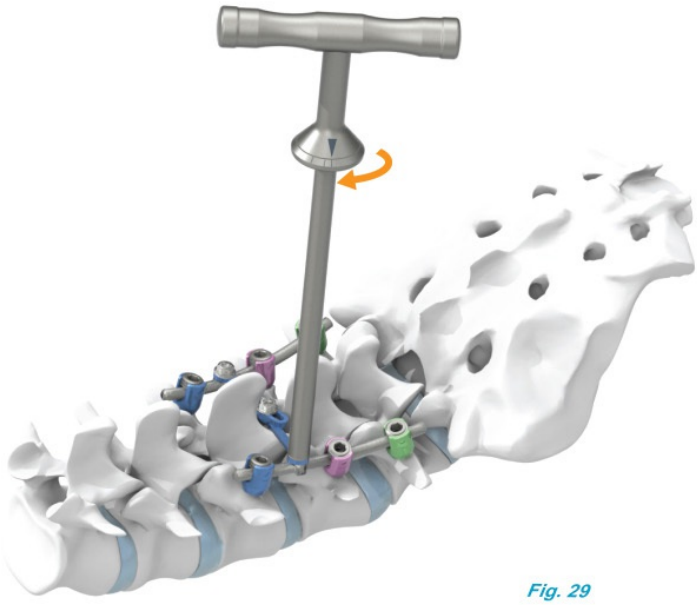


Fig. 29

REVISION or REMOVAL

Instrument	
SF0260	T-LINK HOLDER
SG0032	TORQUE WRENCH FOR T-LINK COLLET TYPE
SF0120	AXIAL TORQUE WRENCH 5 HEX (10N-m)
SF0090	ROD HOLDER
SF0010	POLYSCREW DRIVER
SF0020	MONOSCREW DRIVER

Loosen the side nut using the TORQUE WRENCH FOR T-LINK COLLET TYPE. Then remove the cross link using the T-LINK HOLDER (Fig. 30).

Loosen the set screw using the AXIAL TORQUE WRNECH. Turn counterclockwise to loosen and remove the set screw (Fig. 31).

Note : Use of ANTI-TORQUE DEVICE is recommended to avoid damage to the pedicle.

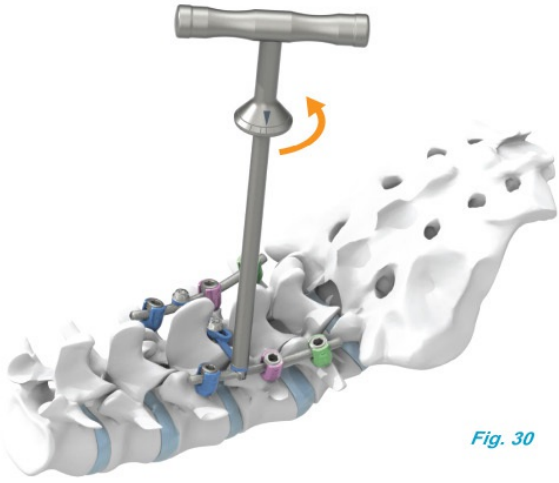


Fig. 30

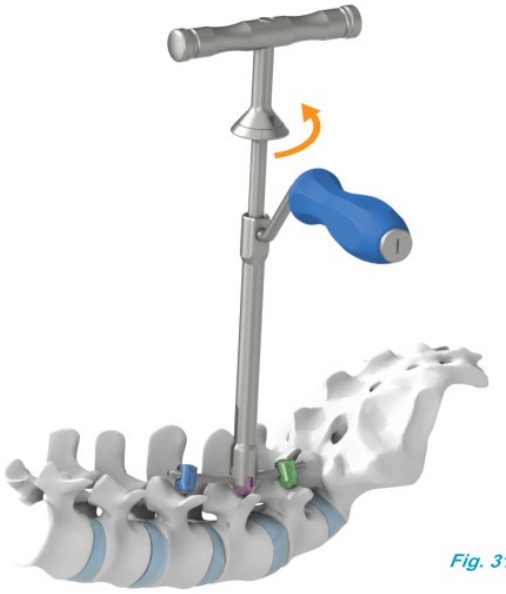


Fig. 31

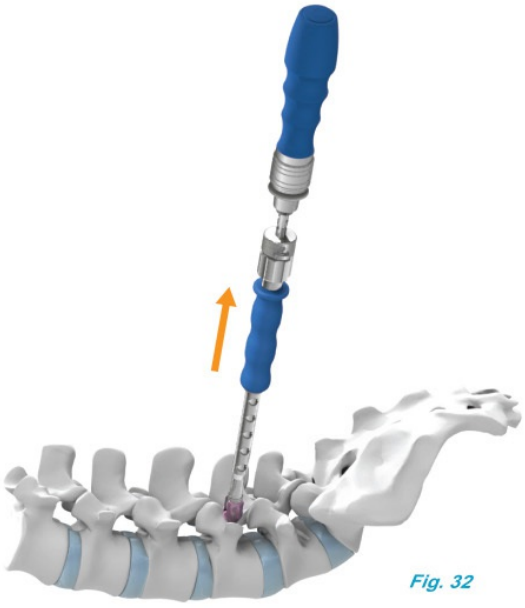


Fig. 32

Remove the rod using the ROD HOLDER.

Remove the polyaxial/monoaxial screw using the polyscrew/monoscrew Driver. Turn counterclockwise slowly. All screws should be removed (Fig. 32).

Note : In revision, use a bigger size screw than previously used.

Ordering Information

Implant (Single-Use Only)

Polyaxial Screw Ø4.0 mm

Cat. No.	Length (mm)
SFA4030	30
SFA4035	35
SFA4040	40
SFA4045	45

Polyaxial Reduction Screw Ø5.0 mm

Cat. No.	Length (mm)
SFRA5035	35
SFRA5040	40
SFRA5045	45
SFRA5050	50

Polyaxial Screw Ø5.0 mm

Cat. No.	Length (mm)
SFA5030	30
SFA5035	35
SFA5040	40
SFA5045	45

Polyaxial Reduction Screw Ø6.0 mm

Cat. No.	Length (mm)
SFRA6035	35
SFRA6040	40
SFRA6045	45
SFRA6050	50

Polyaxial Screw Ø6.0 mm

Cat. No.	Length (mm)
SFA6035	35
SFA6040	40
SFA6045	45
SFA6050	50
SFA6055	55

Polyaxial Reduction Screw Ø7.0 mm

Cat. No.	Length (mm)
SFRA7035	35
SFRA7040	40
SFRA7045	45
SFRA7050	50

Polyaxial Screw Ø7.0 mm

Cat. No.	Length (mm)
SFA7035	35
SFA7040	40
SFA7045	45
SFA7050	50
SFA7055	55

Polyaxial Reduction Screw Ø8.0 mm

Cat. No.	Length (mm)
SFRA8035	35
SFRA8040	40
SFRA8045	45
SFRA8050	50

Polyaxial Screw Ø8.0 mm

Cat. No.	Length (mm)
SFA8040	40
SFA8045	45
SFA8050	50
SFA8055	55

Set Screw for screws

Cat. No.
SF1310

Titanium (Ti) Rods Ø5.5 mm, Straight

Cat. No.	Length (mm)
SF5035TS	35
SF5040TS	40
SF5045TS	45
SF5050TS	50
SF5060TS	60
SF5070TS	70
SF5080TS	80
SF5090TS	90
SF5100TS	100
SF5120TS	120
SF5150TS	150
SF5200TS	200
SF5300TS	300
SF5400TS	400

Cobalt-Chrome (CoCr) Rods Ø5.5 mm, Straight

Cat. No.	Length (mm)
SF5035CS	35
SF5040CS	40
SF5045CS	45
SF5050CS	50
SF5060CS	60
SF5070CS	70
SF5080CS	80
SF5090CS	90
SF5100CS	100
SF5120CS	120
SF5150CS	150
SF5200CS	200
SF5300CS	300
SF5400CS	400

Titanium (Ti) Rods Ø5.5 mm, Curved

Cat. No.	Length (mm)
SF5035TC	35
SF5040TC	40
SF5045TC	45
SF5050TC	50
SF5060TC	60
SF5070TC	70
SF5080TC	80
SF5090TC	90
SF5100TC	100
SF5110TC	110
SF5120TC	120

Cobalt-Chrome (CoCr) Rods Ø5.5 mm, Curved

Cat. No.	Length (mm)
SF5035CC	35
SF5040CC	40
SF5045CC	45
SF5050CC	50
SF5060CC	60
SF5070CC	70
SF5080CC	80
SF5090CC	90
SF5100CC	100
SF5110CC	110
SF5120CC	120

Lateral Connectors, Open

Cat. No.	Length (mm)
SF1511	16.5
SF1512	35

Lateral Connectors, Closed

Cat. No.	Length (mm)
SF1521	16.5
SF1522	35

* Lateral Open and Closed Connectors are assembled with Set screw for screws (SF1310)

Domino Connectors

Cat. No.	
SF1611	2 holes
SF1612	4 holes

Axial Connectors

Cat. No.	
SF1711	2 holes
SF1712	3 holes
SF1713	4 holes

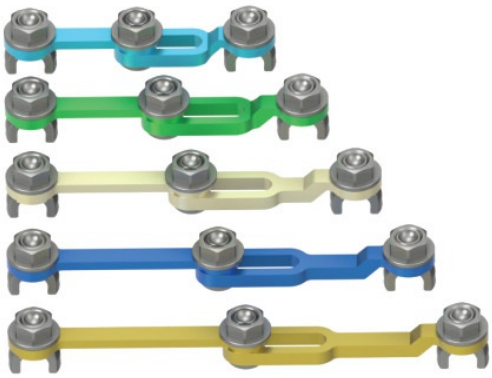
* Axial and Domino Connectors are assembled with Set screw for connectors (SF1320)

Set Screw for connectors

Cat. No.
SF1320

Crosslinks

Cat. No.	Length (mm)
SFTA1410	33-40
SFTA1420	40-50
SFTA1430	50-60
SFTA1440	60-70
SFTA1450	70-80

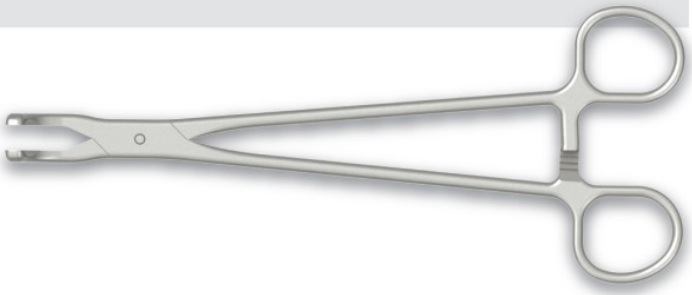


Instruments

SG0001
AWL

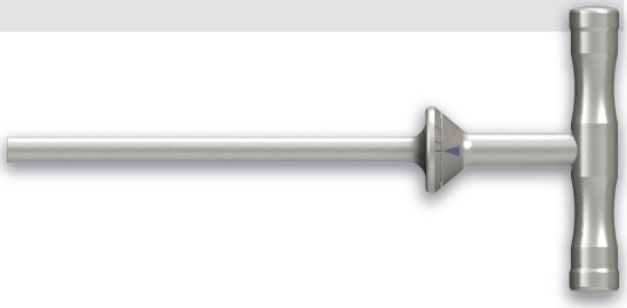
SN0042
SCREW ADJUSTMENT INSTRUMENT

SN0009
HOUSING HOLDER



SP0040
FD RATCHET HANDLE

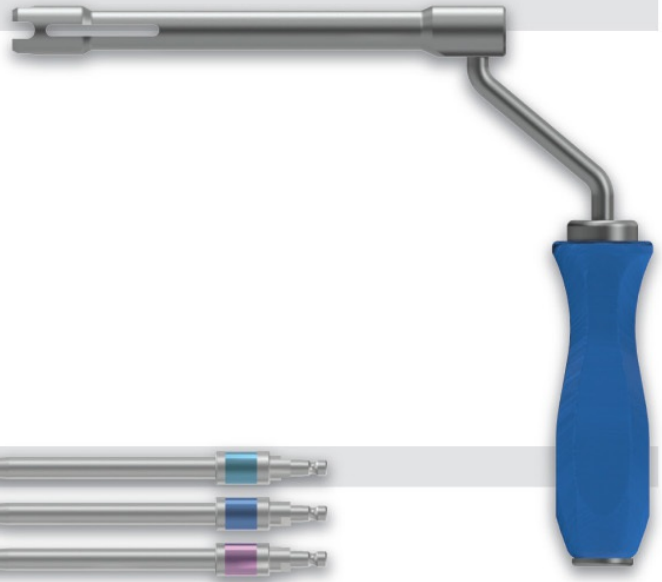
SG0032
TORQUE WRENCH FOR T LINK COLLET TYPE



SF0010
POLYSCREW DRIVER

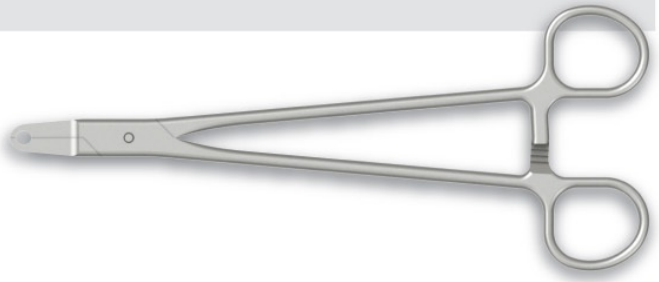
SF0020
MONOSCREW DRIVER

SF0030
ANTI-TORQUE DEVICE



SF0040 TAP 4.0
SF0050 TAP 5.0
SF0060 TAP 6.0
SF0070 TAP 7.0
SF0080 TAP 8.0

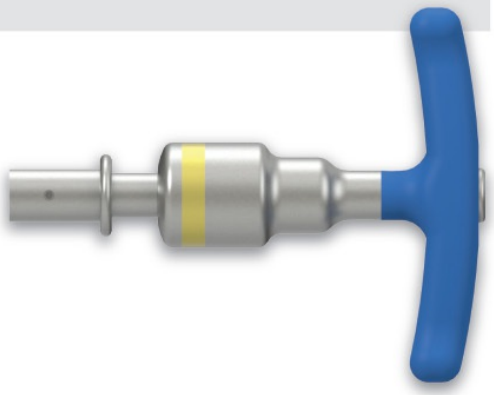
SF0090
ROD HOLDER



SF0100
ROD BENDER

SF0110

TORQUE LIMITING T-HANDLE (10N-m)

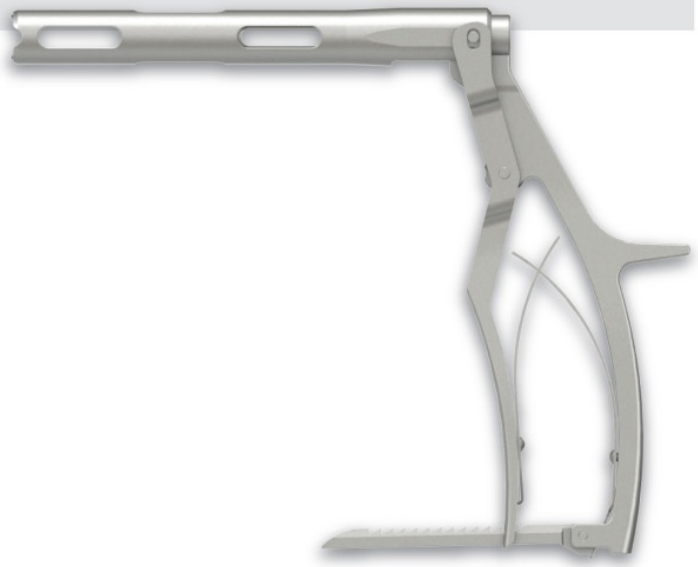


SF0120

AXIAL TORQUE WRENCH 5 HEX (10N-m)

SF0130

PERSUADER



SF0140

ANAX REDUCTION HOUSING CUTTER

SF0150

POLY HEAD ADJUSTER

SF0160

SET SCREW DRIVER GUIDE

SF0170

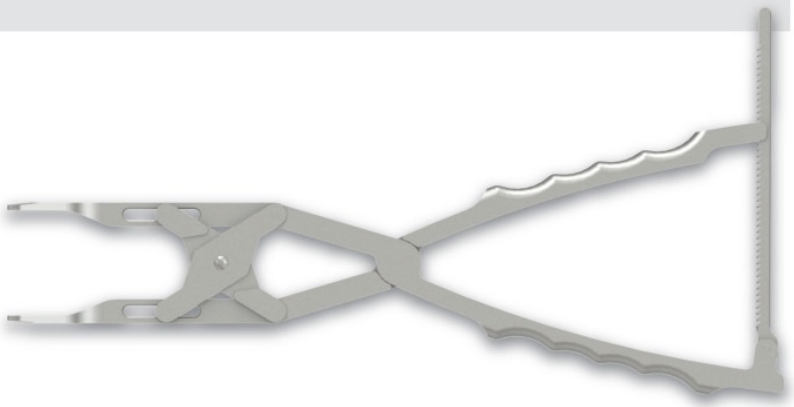
IN-SITU ROD BENDER - RIGHT

SF0180

IN-SITU ROD BENDER - LEFT

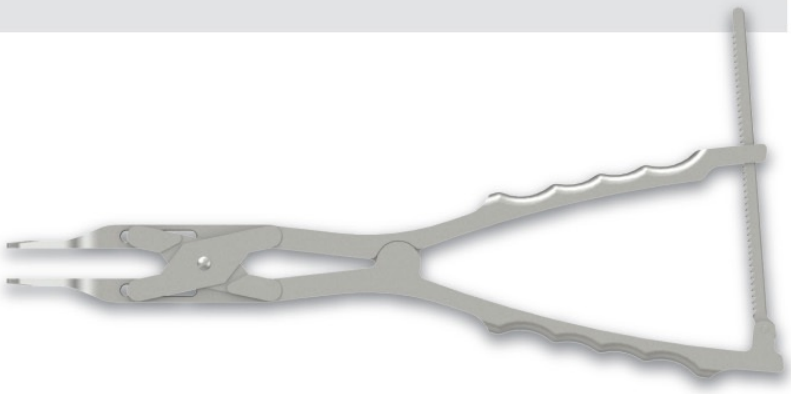
SF0190

COMPRESSOR for 5.5mm ROD



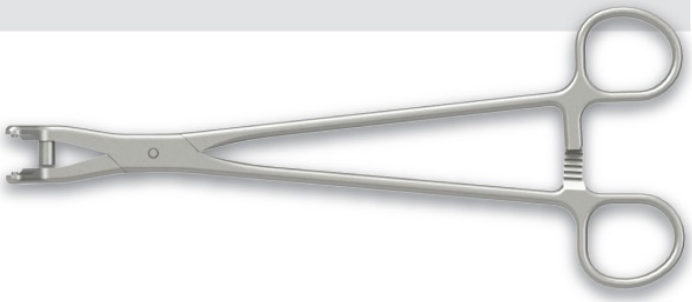
SF0200

SPREADER for 5.5mm ROD



SF0210
DEROTATOR

SF0220
ROCKER



SF0230
5mm DRIVER WITH ADAPTOR

SF0240
GUIDE PIN - LEFT

SF0250
GUIDE PIN - RIGHT

SF0260
T-LINK HOLDER

SF0270
ROD PUSHER

SF0280

STRAIGHT PROBE

SF0290

CURVED PROBE

SF0300

TESTER - STRAIGHT

SF0310

TESTER - CURVED

Important Information on the ANAX™ 5.5 Spinal System

Important Note
The users of the *ANAX™ 5.5 SPINAL SYSTEM* acknowledge that they have read and agreed to the conditions in this insert, which are considered to be contractual.

Basic Structure
The *ANAX™ 5.5 SPINAL SYSTEM* is an internal fixation device for spinal surgery comprising pedicle screws, rods, set screws, connectors and transverse link assemblies. Various forms and sizes of these implants are available, so that adaptations can be made to take into account the pathology and individual patient.

Material
The *ANAX™ 5.5 SPINAL SYSTEM* components are fabricated from medical grade titanium alloy (ASTM F136) and medical grade cobalt-chromium-molybdenum alloy (ASTM F1537).

Never use stainless steel and titanium implant components in the same construct. Titanium alloy and medical grade cobalt-chromium-molybdenum alloy may be used together. Never use titanium alloy and/or medical grade cobalt-chromium-molybdenum alloy with stainless steel in the same construct.

Indications for Use
The *ANAX™ 5.5 SPINAL SYSTEM* is a posterior, noncervical pedicle fixation system intended to provide immobilization and stabilization of spinal segments in skeletally-mature patients as an adjunct to fusion by autogenous bone graft in the treatment of the following acute and chronic instabilities or deformities of thoracic, lumbar and sacral spine:

- Spondylolisthesis (Grade 3 and 4)
- Degenerative spondylolisthesis with objective evidence of neurological impairment
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

Note : The ANAX™ 5.5 SPINAL SYSTEM Surgical Technique Manual should be followed carefully. Important information on the proper usage of implants and instruments is included.

Levels of Fixation
Levels of fixation are for the thoracic, lumbar and sacral spine.

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 neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
- Potential risks associated with the use of this system, which may require additional surgery, include device component fracture, loss of fixation, non-union, fracture of the vertebra, neurological injury and vascular or visceral injury.
- Discard all damaged or mishandled implants.
- Never reuse an implant even though it may appear undamaged.
- Internal fixation devices cannot withstand activity and loads equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result.
- Reuse of an implant may cause the cross infection of the patients.
- Contouring or bending of a screw or hook may reduce its fatigue strength and cause failure under load. If spinal screws or hooks are bent or otherwise damaged during insertion or adjustment, they may not be implanted and must be replaced. Rods should only be contoured with the proper contouring instruments. Incorrectly contoured rods or rods which have been repeatedly or excessively contoured must not be implanted.
- Mixing Metal: Some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants and the amount of metal compounds released into the body system may also increase. Internal fixation devices such as rods, screws, hooks, etc., which come into contact with other metal objects must be made from like or compatible metals.
- Because different manufacturers employ different materials, varying tolerances, manufacturing specifications and differing design parameters, components of the *ANAX™ 5.5 SPINAL SYSTEM* should not be used in conjunction with components from any other manufacturer's spinal systems. Any such use will negate the responsibility of U&i Corporation for the performance of the resulting mixed component implant.
- Removal of an unloosened spinal screw may require the use of special instruments to disrupt the interface at the implant surface. This technique may require practice in the laboratory before being attempted clinically.
- Any decision by a surgeon to remove the internal fixation device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.
- Implant removal should be followed by adequate postoperative management to avoid fracture.

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 systems because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- The surgeon should consider the level of implantation, the weight of the patient, the patient's activity level or general conditions and any other factor which may have an impact on the performance of the system based on published fatigue test results of the system.
- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting or muscle strain), resultant forces can cause failure of the device.
- In some cases, progression of degenerative disease may also be so advanced at the time of implantation that they may substantially decrease the expected useful life to the appliance. In such cases, orthopedic devices may be considered only as a delaying technique or to provide temporary relief.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the spinal fixation system. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions and potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre and post-operative patient management are considerations essential to a successful surgical outcome.
- Patients should be instructed in detail about the limitations of the implants, including but not limited to the impact of excessive loading through patient weight or activity, and should be taught to govern their activities accordingly. The patient should understand that a metallic implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.
- Appropriate selection, placement and fixation of the spinal system components are critical factors which affect implant service life. As in the case of all prosthetic implants, the durability of these components is affected by numerous biologic, biomechanics and other extrinsic factors, which limit service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life. (Note : While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape and strength of the implants.)
- Care must be taken to protect the components from being marred, nicked or notched as a result of a contract with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant.
- 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 impact on the performance of the system.
- Sale of this product is restricted to physicians.

General Conditions of Use
- The implants must be implanted only by surgeons having undergone the necessary training in spinal surgery. Their use in implantation must be decided upon in accordance with surgical and medical indications, the potential risks and limitations related to this type of surgery, the contraindications, side effects and precautions. The surgeon should also possess knowledge of the metallurgic and biological characteristics of the implants.
- It is recommended that the *ANAX™ 5.5 SPINAL SYSTEM* not be used in conjunction with implants from a different source, a different manufacturer or made from a different material. If this should occur, U&i Corporation declines all responsibility.
- Under no circumstances may the implants be re-used. Although the device may appear intact on removal, internal modification due to the stress and strains placed on it, or small defects may exist which may lead to fracture of the implant.

Contraindications
- Any active or suspected latent infection in or about the spine.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in post-operative care.
- Bone stock compro mised by disease, infection or prior implantation which cannot provide adequate support and or fixation to the implant.
- Obesity, an overweight or obese patient can produce loads on the spinal system which can lead to failure of the fixation of the device or to failure of the device itself.
- Recent infection, fever or leukocytosis
- Bony abnormalities preventing safe screw fixation
- Open wounds
- Metal sensitivity, documented or suspected
- Bone absorption, osteopenia and/or osteoporosis
- Patients having inadequate tissue coverage over the operative site
- Pregnancy
- Excessive local inflammation
- Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count, (WBC) or marked left shift in the WBC differential count.

Side Effects
- Late bone grafting or no visible fusion mass and pseudarthrosis
- Neurological complication, paralysis, soft tissue lesions, pain due to the surgical procedure, breakage deformation and or migration of the implant
- Pedicle failure while preparing and inserting the pedicle screw
- Superficial or deep-set infection and inflammatory phenomena
- Allergic reaction to the Ti6Al4V ELI alloy and cobalt-chromium-molybdenum alloy
- Reduction in bone density due to different distribution of mechanical stresses
- Pain and abnormal sensations due to hardware bulkiness
- Neurological and spinal dura matter lesions from surgical trauma
- Bursitis
- Presence of micro-particles around the implants
- Growth of the fused vertebrae is altered
- Partial loss of the degree of correction achieved during surgery
- Modification of spinal curvature and stiffness of the vertebral column
- The above list of side effects is not exhaustive. These side effects can sometimes necessitate further surgical treatment.

Packaging, Labeling and Storage
- Implants removed from a patient of that contact bodily tissues or fluids should never be reused.
- The implants are delivered in packages. These must be intact at the time of receipt. All the legal information required for this type of implant is given in the labeling of each package.
- Implants may be delivered as a complete set, in specially designed trays or in boxes which can be sterilized directly.
- Use care in handling and storage of implant components. Cutting, sharply bending or scratching the surface can significantly reduce the strength and fatigue resistance of the implant system. This, in turn, could induce cracks and/or non-visible internal stresses that could lead to fracture of the implants. Implants and instruments in storage should be protected from corrosive environments such as salt air, moisture, etc. Inspection and trial assembly are recommended prior to surgery to determine if the instruments or implants have been damaged during storage or prior procedures.

Cleaning and Sterilization Procedures:
Manual Cleaning Procedure
1. Use the neutral pH enzyme soaking solution that has been prepared.
2. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes.
   Use a soft-bristled brush to gently clean the device (particular attention shall be given to crevices, lumens, mated surfaces and other hard-to-clean areas) until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush).
   Note: The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid).
3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
4. Prepare the neutral pH cleaning (detergent) solution and place in a sonication unit.
5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz.
6. Rinse instrument in purified water (from one or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream.
7. Repeat Steps 5 and 6 with freshly prepared cleaning solution.
8. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.

Automated Cleaning Procedure
Automated washer/disinfector systems are not recommended as the sole cleaning method for complex surgical instruments. These instruments should be cleaned following the manual cleaning procedure above. An automated system may be used as a follow-up method but is not required.
- CAUTION : Use of sodium hydroxide (NaOH) is prohibited. Use of corrosive products and/or instruments including abrasive sponges and metal brushes should be avoided.
- Visually inspect the devices under normal room lighting condition to verify all foreign debris has been removed.
- Verify that the instruments are in operation condition.

Sterilization Procedure
- *All implants and instruments of the ANAX™ 5.5 SPINAL SYSTEM are provided non-sterile.*
- Recommended method to achieve a degree of sterility equal to at least 10-6. Sterilize by the autoclaving procedure regularly used in the hospital.

	Steam condition	Temperature	Sterilization time	Drying time
Method 1	Steam, Gravity Cycle	132℃ (270°F)	20 min	15 min
Method 2	Steam,Pre-vacuum Cycle	132℃ (270°F)	4 min	15 min

Safety and Conditionality in the MR Environment
- The *ANAX™ 5.5 SPINAL SYSTEM* has not been evaluated for safety and compatibility in the MR environment.
- The *ANAX™ 5.5 SPINAL SYSTEM* has not been tested for heating or migration in the MR environment.

Calibration Specifications
It is recommended that the torque wrenches receive periodic calibration and maintenance at a qualified facility. See the table below for recommended calibration cycles. The calibration cycle is based on expected amount of use in a given period.

Description	Part Number	Calibration Range	Calibration Cycle
Torque limiting T-handle(10N-m)	SF0110	9.5 ~ 11 N-m	10 months

Guarantee
The guarantee is only applicable if the device is used in accordance with normal conditions as defined in these instructions and in conformity with the recommended surgical technique

U&i CORPORATION CE 0434

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