

# SmartLoc<sup>®</sup>

## Evolution System

*Technique Guide*



Advancing Spine Technology

 **A-SPINE**



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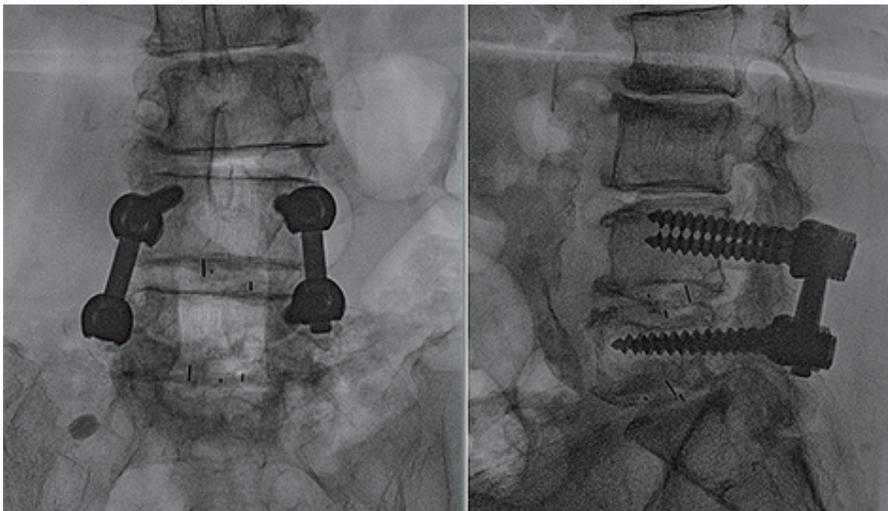
# Indication

- Degenerative spondylolisthesis with distinctive evidence of neurological impairment
- Vertebral fracture
- Spinal tumor
- Dislocation
- Scoliosis
- Kyphotic deformity
- Discogenic deformity
- Failed previous fusion

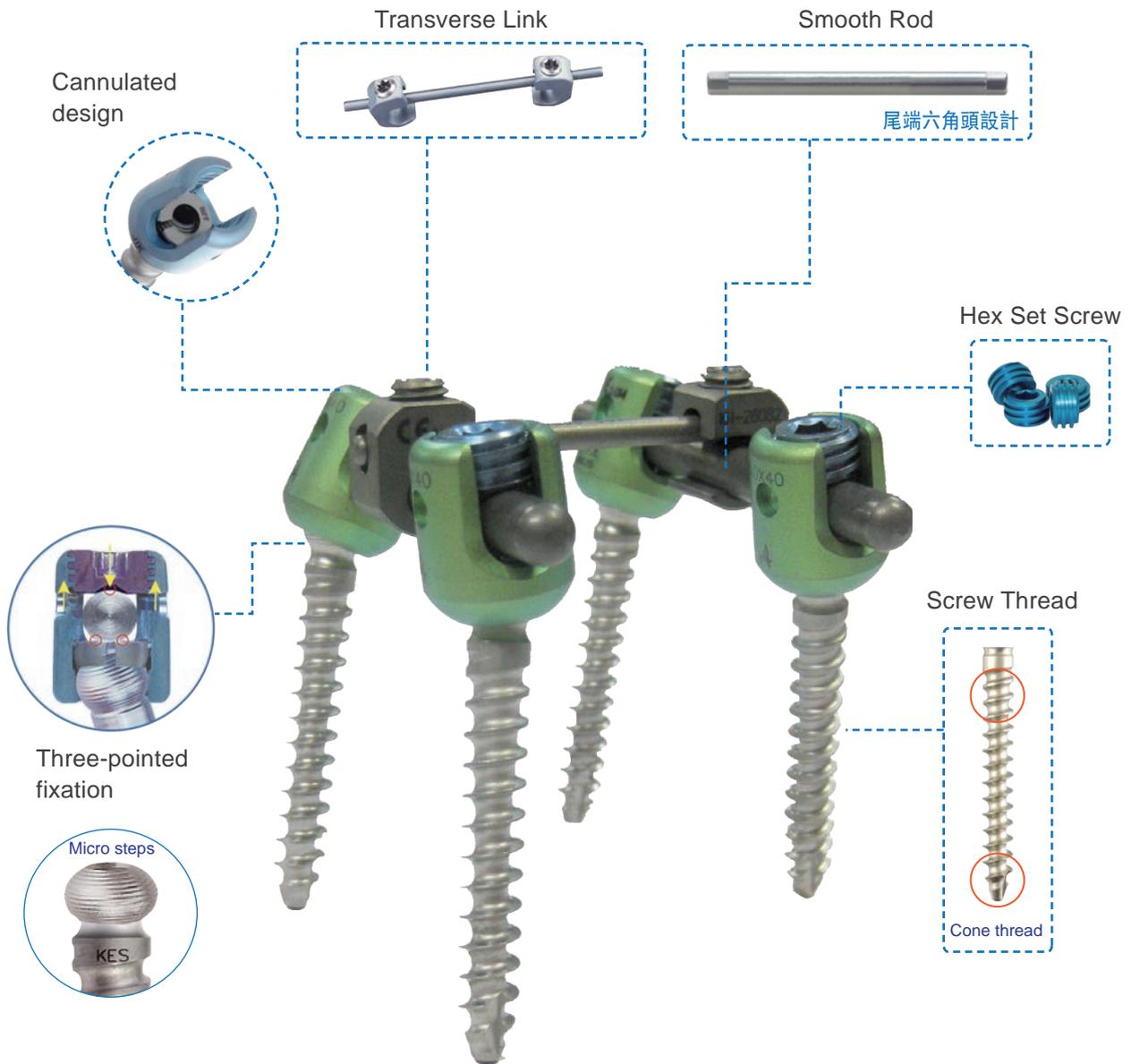
# Contraindications

- Bone absorption, osteopenia, and/or osteoporosis
- Any active or suspected latent infection of the spine
- Any mental or neuromuscular disorder which might create unacceptable risk of fixation failure or complications post-operatively
- Bone stock abnormalities, or deficiency which cannot provide adequate support and/or fixation to the implants
- Pathological obesity
- Open wounds
- Metal sensitivity, documented or suspected
- Pregnancy
- Excessive local inflammation reaction
- Other medical or surgical symptoms that may preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplainable by other diseases, elevation of white blood count WBC), or marked left shift in the WBC differential count

## Clinical case-Postoperative



# System Overview



# Screw

## Screw

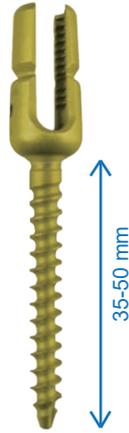
Monoaxial Screw

φ 5.5-7.0 mm



Monoaxial Long-Arm Screw

φ 6.0-7.0 mm



Polyaxial Screw

φ 5.5-7.0 mm



Polyaxial Long-Arm Screw

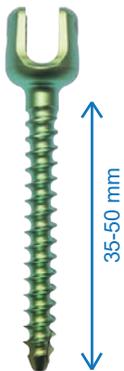
φ 6.0-6.5 mm



## Screw (Cannulated)

Monoaxial Cannulated Screw

φ 5.5-7.0 mm



Monoaxial Long-Arm Cannulated Screw

φ 6.0-7.0 mm



Polyaxial Cannulated Screw

φ 6.0-6.5 mm



Polyaxial Long-Arm Cannulated Screw

φ 6.0-6.5 mm



## System Overview



Lamina Hook



Offset Hook Left



Domino Connector Block (Short)



Pedicle Hook



Offset Hook Right



Axial Connector Block



# Instruments



406-0101

T-Handle



406-0201

Awl (With Stop)



406-0301

Probe



406-0401

Sensor



407-0501  
407-0502

5mm Tap  
6mm Tap



407-0505  
407-0506

4mm Tap \*Option  
7mm Tap \*Option



406-1301

Rod Holder



406-2601

Rod Pusher



406-3005

5mm Rotator Bar



406-3104  
406-3114 ( Wavy Bar )

4mm Guide Pin



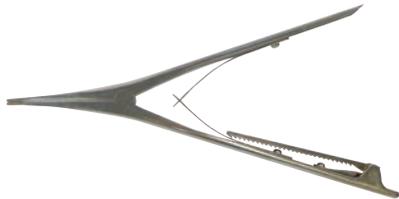
407-3310

4mm Hex Screw Driver



407-0901

Angled Compressor



407-0902

Angled Distractor



407-2102

Long Arm Cutting Forceps



407-2101

Rod Clamp



407-2901

Rod Template  
150mm



407-3402

Anti-Torque Wrench



407-3313

3.5mm Polyaxial  
Screw Driver



407-3316

3.5mm Poly Longarm Driver



407-3302

Top Loading  
Screw Driver



406-0836

3.5mm Adjust Driver



407-1301

Set Screw Holder



406-1201

Rod Bender  
(French Bender)



407-2902

Rod Template  
300mm



407-1001

Torque Limiting T-Handle



412-3101

T20 Screw Wrench



407-3309

4mm Hex  
Screw Driver



407-1403

Rod Introducer



406-1203

Insitu Bender



407-0104

Ball Handle, Ratchet



20141-022

SmartLoc Block



407-0503  
407-0504

5mm Cannulated Tap  
6mm Cannulated Tap



407-3315

3.5mm Cannulated  
Adjust Driver



407-3314

Cannulated Poly  
Screw Driver



407-3317

Cannulated Poly  
Longarm Driver



407-1106

Guide Wire ( Ø1.5mm x 500mm)



407-1105  
407-1107

Guide Wire ( Ø1.5mm x 450mm) \*Option  
Guide Wire ( Ø1.0mm x 450mm) \*Option

#### STERILIZATION:

The implants and instruments are delivered non sterile. Before use needed cleaned and sterilized recommended to be steam sterilized refer to "A-SPINE Reprocessing Manual" following process parameters:

Steam Wrapped Gravity Cycle at 121 °C/250 °F for 30 minutes.

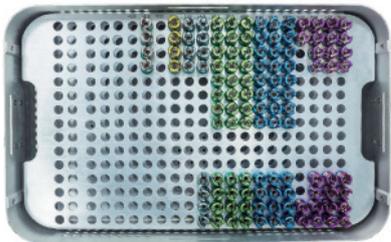
If need more information, the "Intended for Use" and "A-SPINE Reprocessing Manual" can be downloaded from A-SPINE official website: <http://www.aspine.com.tw/>

# Standard Trays

## Implant Trays



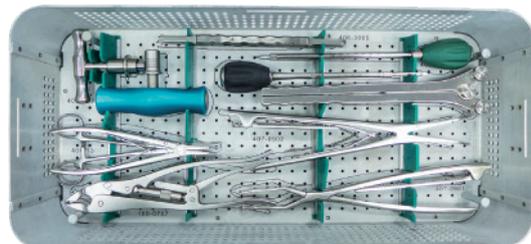
99902-021



## Instrument Trays



99902-022



# Surgical Technique

## Patient Positioning

The patient is positioned on a Spinal Frame in the prone position, using a four-point support. The Spinal frame is used to allow free suspension of the abdomen, and to avoid compression of the major blood vessels. Hypotensive anaesthesia and auto transfusion may also be used to reduce intraoperative blood loss.

The use of image intensifier with C-arm is recommended intraoperatively. Prior to prepping and draping, the patient's position should be checked with the C-arm to determine the axial direction of the pedicles, and to confirm that clear images of the affected levels are obtainable. The patient is subsequently prepped and draped using standard technique. (Figure 1)

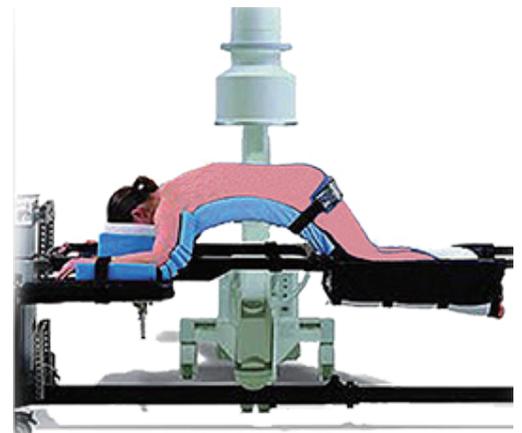


Figure 1

## Locate the Pedicle Entry Points (Figure 2)

The use of the SmartLoc Evolution System in spinal surgery requires a working knowledge of anatomic subtleties in order to identify the pedicles accurately.

In the lumbar spine, the pedicle is located where the line bisects the base of the transverse process. The second line goes through the lateral aspect of the superior articular facet and parallel with the mid-line. The facet osteophytes need to be removed in order to delineate the true position of the pedicle.

Current literature suggests that the screws in the lower lumbar spine should be placed away from the facet joint to avoid interference with the motion of uninstrumented and unfused segments. The preferred entrance point locates at the lateral and inferior corner of the superior articular facet.

The entry point of sacral fixation located at inferior lateral aspect of the L5-S1 facet joint, converging toward the center of the promotory with sagittal inclination parallel to the S1 superior endplate.

If indicated, secondary fixation in S1 is possible by the divergent Tri-Fix Self Locking Screw toward the sacral ala adjacent to the primary sacral screw.

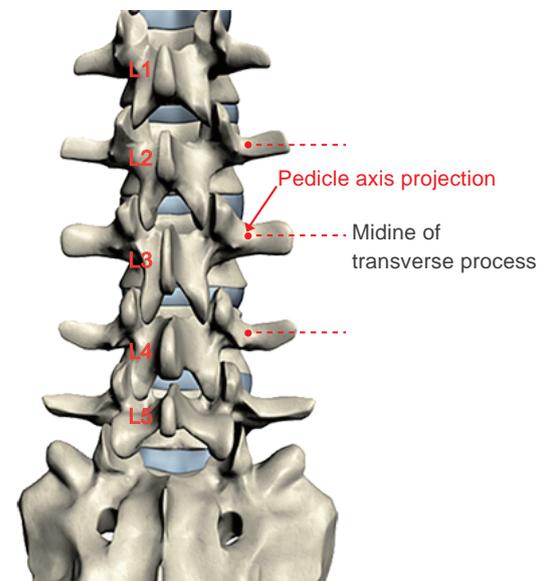


Figure 2

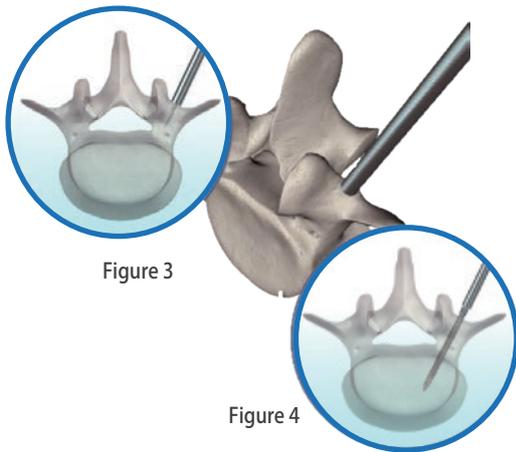


Figure 3

Figure 4

## Pedicle Preparation

The point of entrance to the pedicle is identified and lateral imaging with C-arm fluoroscopy is used to confirm position and provide reference for subsequent placement of pedicle. Care is taken upon broaching pedicles so that the angle of the approach corresponds to that demonstrated on lateral imaging.

Determine the angle of entry and penetrate the pedicle cortex with the Awl(406-0201) to mark that position. (Figure 3) Upon completion of probing of all pedicles with the assistance of fluoroscopy.

Using the Probe(406-0301) gently deepen the hole through the soft cancellous bone to the desired depth. (Figure 4) The probe is placed through the pedicle into the body of the vertebrae with C-arm Fluoroscopy assistor approximately. In certain cases such as with osteoporotic bone, the probe is not used but a 4mm Guide Pin(406-3104/406-3114) is placed directly into the pedicle and vertebral body

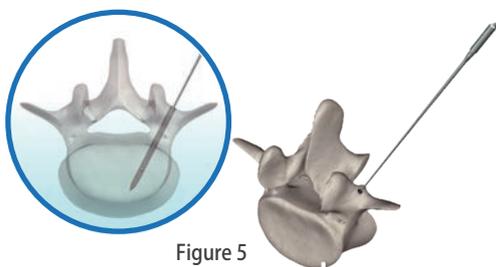


Figure 5

The Sensor(406-0401) is used to confirm the continuity of the cortical wall of the pedicle and position of the pedicle passage is indicated. (Figure 5)



406-0201

406-0301

406-0401

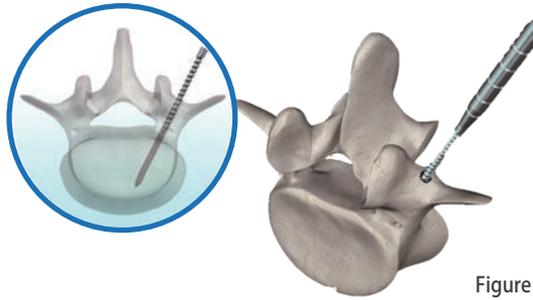


Figure 6

For convenience, the T-Handle (406-0101) or Ball Handle (407-0104) is attached to instrument.

If necessary, prepare the pedicle canal using the appropriate tap according to the following reference table.

If use the Guide Wire (407-1105~407-1107) to make sure the position, choose the Cannulated Tap (407-0503/407-0504) to prepare the pedicle canal. (Figure 6).

Dia. of Screw (mm)	Instruments	Item No.	Item No. (Cannulated)
6.0 and 6.5	5mm Tap	407-0501	407-0503
7.0 and 7.5	6mm Tap	407-0502	407-0504
5.0 and 5.5	4mm Tap	407-0505*	
8.0	7mm Tap	407-0506*	

\*Option



Guide Wire		
Ø	Length	Item No.
1.5mm	450mm	407-1105*
1.5mm	500mm	407-1106
1.0mm	450mm	407-1107*

\*Option



## Inserting Screw

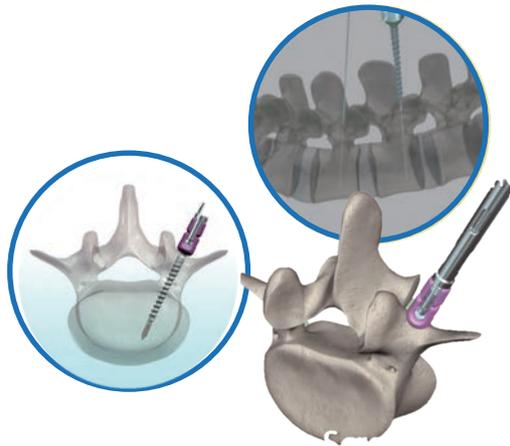


Figure 7

The appropriate screw is mounted and fastened onto the screw driver.  
 Tip of the cannulated screw is placed follow guide wire into the pedicle entry point. (Figure 7)  
 The screw with the features of self-tapping tip for penetration easy into pedicle .

407-3302



407-3313



407-3316



Type of Screw	Instrument	Item No.
Monoaxial (Long-Arm)	Top Loading Screw Driver	407-3302
Polyaxial	3.5mm Polyaxial Screw Driver	407-3313
Polyaxial Long-Arm	3.5mm Poly Longarm Driver	407-3316
Polyaxial Cannulated	Cannulated Poly Screw Driver	407-3314
Polyaxial Cannulated Long-Arm	Cannulated Poly Longarm Driver	407-3317

When fully seated, the pedicle screws are positioned at depth of 50% to 80% of the vertebral body, paralleling the superior end plates. The 3.5mm Hex Screw Driver (406-0836) or 3.5mm Cannulated Adjust Driver (407-3315) can be used to adjust the polyaxial screws quickly.

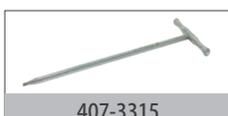
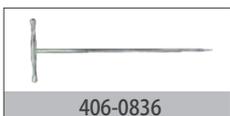




Figure 8

## Bending the Rod

The Rod Template (407-2901/407-2902) may be used to estimate the length and curvature of the rod. The appropriate length rod can be bent using the Rod Bender (406-1202). (Figure 8)

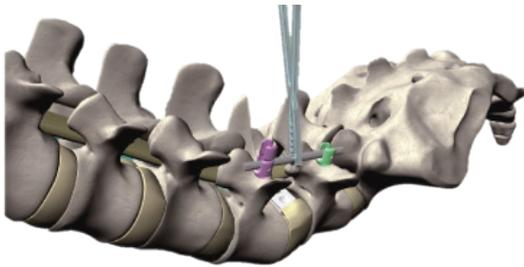


Figure 9

## Rod Introduction

The Rod Holder (406-1301) is used to hold the rod and introduce it into the head of the screw. (Figure 9)

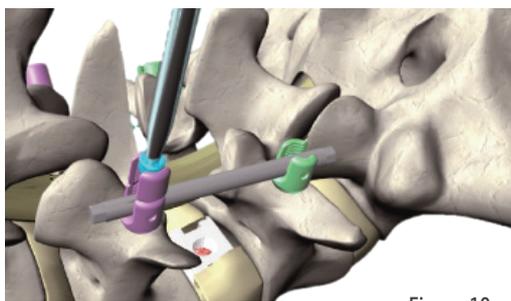
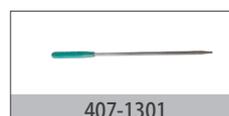


Figure 10

## Set Screw Introduction

The Set Screw Holder(407-1301) is used to introduce the set screw into the screw head and for provisional tightening. Using the 4mm Hex Screw Driver(407-3309) lock the star set screw and fix it over the inserted screw. The Rod Pusher(406-2601) can also help you fix the rod when you locking the star set screw. (Figure 10)



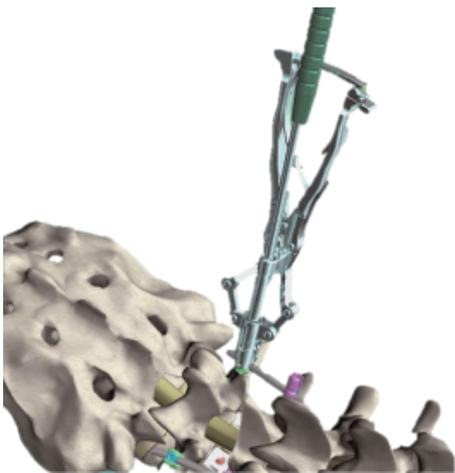


Figure 11

## Rod Introducer

If necessary, the Set Screw Holder(407-1301) could be used with the Rod Introducer(407-1403).

Rod Introducer can persuaded the unsettled rod around the cup head of the polyaxial or monoaxial standard screw. When using the Rod Introducer, apply to the screw cup side hole to match the tool end of hemi circular within have two post.

Squeeze and compression Rod Introducer to ensure the rod is fully seated of the screw head. (Figure 11)

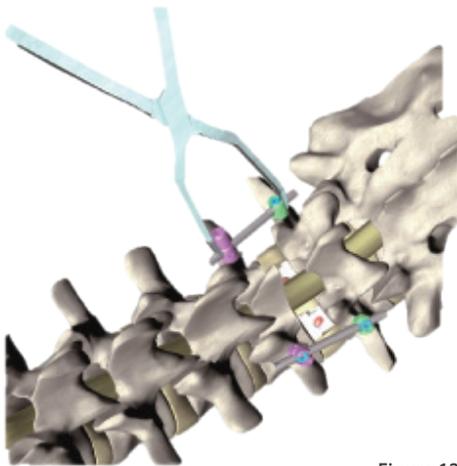


Figure 12

## Distraction and Compression

Distraction and compression is achieved though use of the Angled Distractor (407-0902) and the Angled Compressor(407-0901).

The set screws can be subsequently tightened starting at the superior and inferior ends of the rod followed by tightening the adjacent set screws in between. (Figure 12)



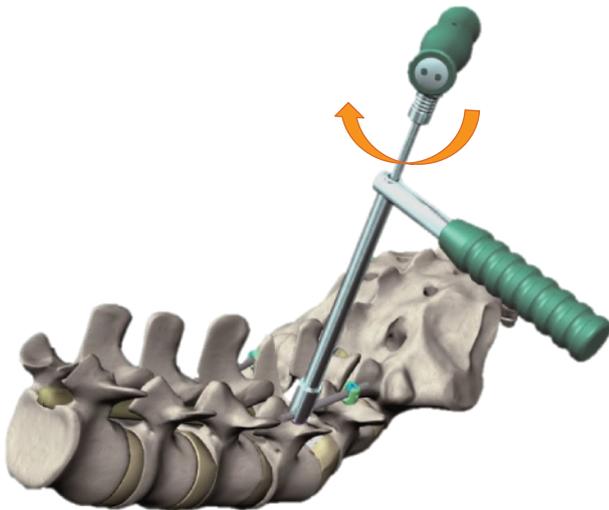


Figure 13

## Final Tightening

Assemble the 4mm Hex Screw Driver (407-3310) and Torque Limiting T-Handle(407-1001) for final tightening the set screw.

The 4mm Hex Screw driver is inserted through the Anti-Torque Wrench(407-3402) in order to provide resistance to rotational torque during final tightening. (Figure13)

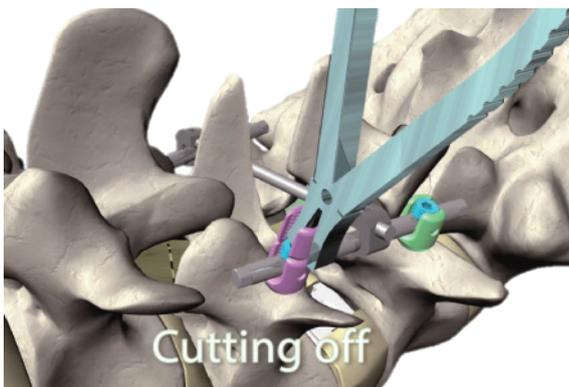
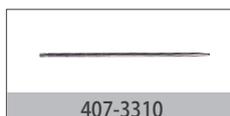


Figure 14

## Removal of Reduction Tabs

The Long Arm Cutting Forceps(407-2102) is used to remove the remaining tab of the Long-Arm screws. (Figure 14)



## Transverse Link

When required, Transverse Links can be assembled to assist with construct stability. The Transverse Link can be applied to resist rotational and lateral bending forces of the vertebral column for multi-level constructs.

The Transverse Rod may be bent to match the axis of the rods. The set screw of the Transverse Link is tightened using the T20 Screw Wrench (412-3101). (Figure15)

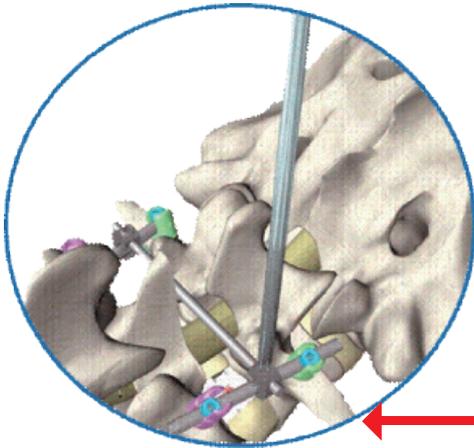


Figure 15



## Implant Removal

- The Hex Set Screw removal  
The 4mm Hex Driver(407-3309) is used to remove the set screws.
- Monoaxial/ Polyaxial Screw removal  
The T-Handle (406-0101) in combination with the Monoaxial Screw Driver(407-3302) or the Polyaxial Screw Driver(407-3313) is used to remove the Monoaxial/ Polyaxial Screw.



Three points fixation  
monoaxial & polyaxial screws



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