

SmartLoc[®] Evolution System



+ Characteristics

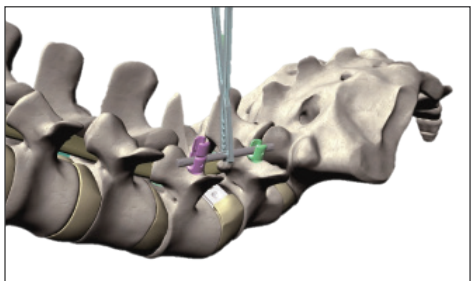
- Easy & Stability
- Top-loading System
- Three Points Fixation Monoaxial & Polyaxial Screws

Contents



Indication 2

Contraindications 2



Surgical Technique 3

Instrument Set 12



Instruments 15

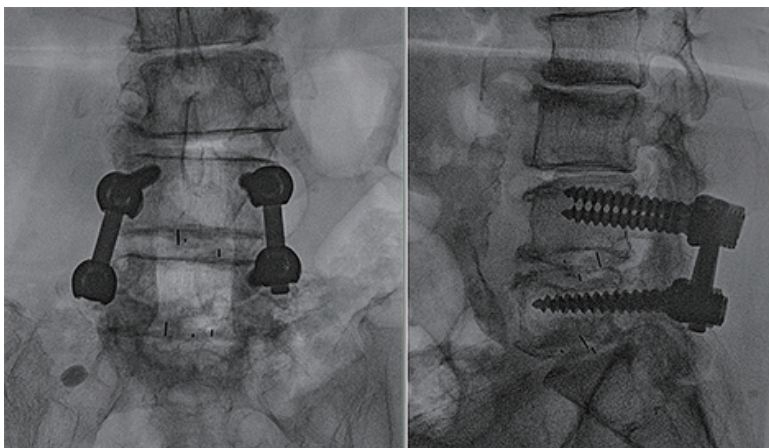
Indication

- Degenerative disc disease
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- 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

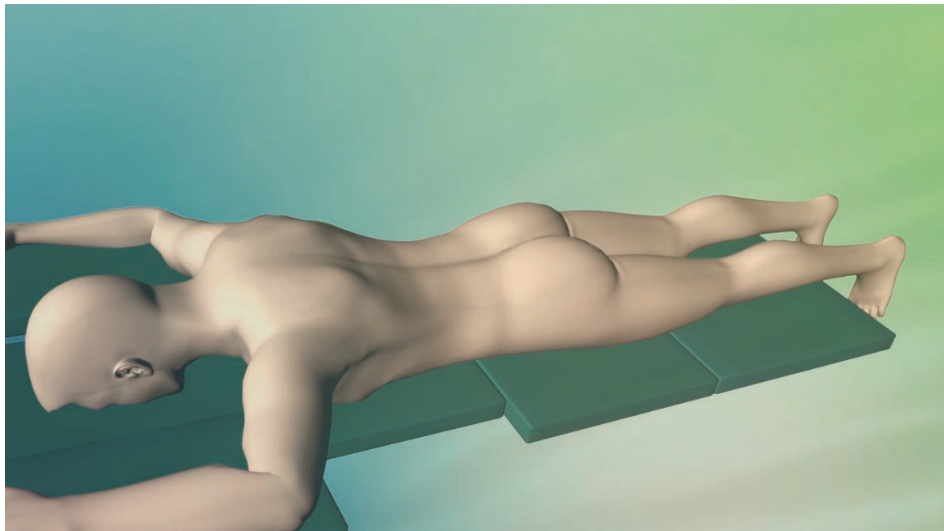


Surgical Technique

○ 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.



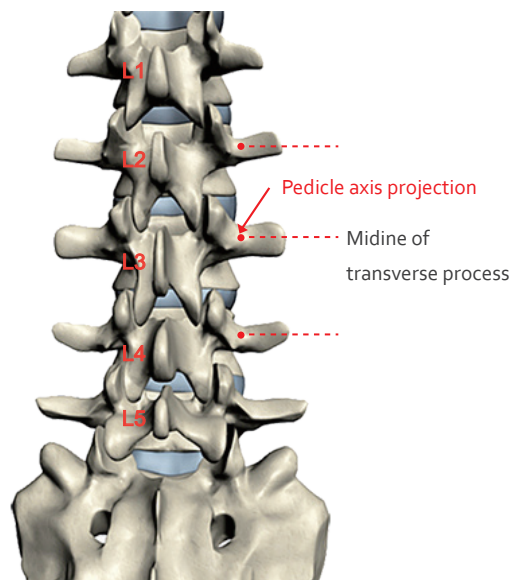
○ Locate the Pedicle Entry Points

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 promontory 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.



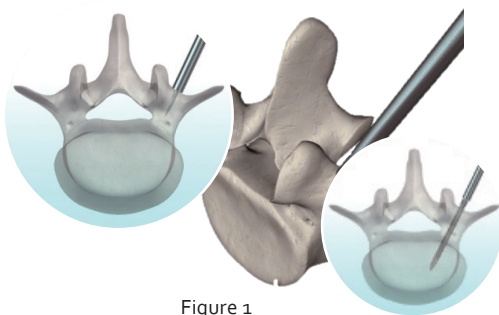


Figure 1

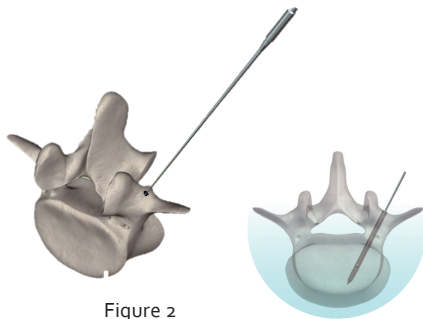


Figure 2

01 Pedicle Preparation(1/2)

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. (Fig. 1) 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. (Fig. 1) 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

02 Guide Wire Placement (2/2)

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. (Fig. 2)



406-0201

Awl
(With Stop)



406-0301

Probe



406-0401

Sensor

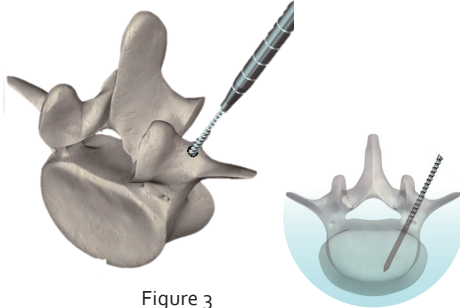


Figure 3

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. (Fig. 3).

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
1.5mm	450mm	407-1107*

*Option



406-0101

T-Handle



407-0104

Ball Handle, Ratchet

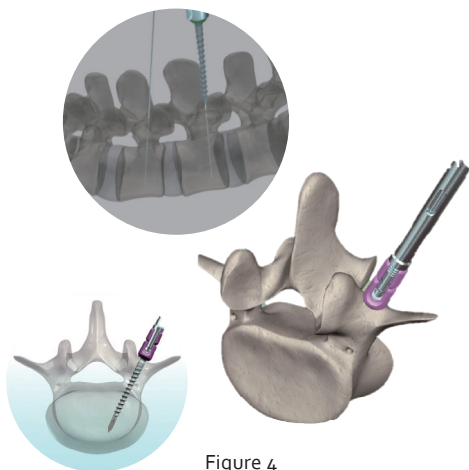


Figure 4

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. (Fig. 4).

03 Inserting Screw

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. (Fig. 5).

The screw with the features of self-tapping tip for penetration easy into pedicle .



When fully seated, the pedicle screws are positioned at depth of 50% to 80% of the vertebral body, parallelling 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.

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

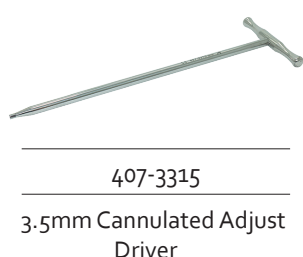
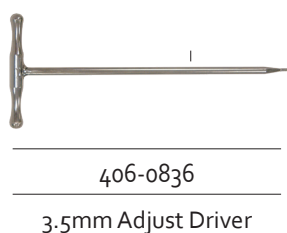




Figure 5

04 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)**. (Fig. 5).

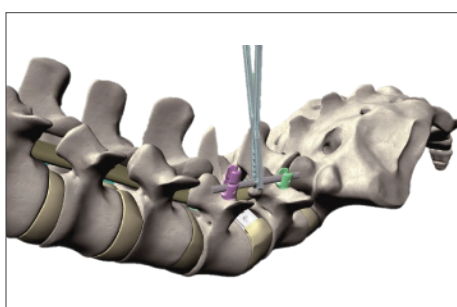


Figure 6

05 Rod Introduction

The **Rod Holder (406-1301)** is used to hold the rod and introduce it into the head of the screw. (Fig. 6).

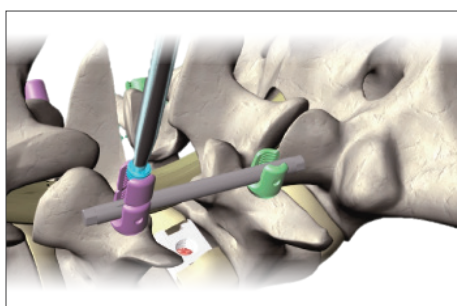


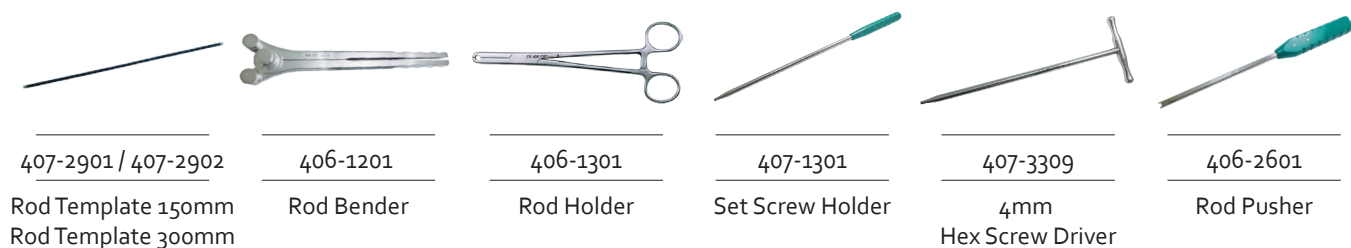
Figure 7

06 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. (Fig.7).



407-2901 / 407-2902

Rod Template 150mm
Rod Template 300mm

406-1201

Rod Bender

406-1301

Rod Holder

407-1301

Set Screw Holder

407-3309

4mm
Hex Screw Driver

406-2601

Rod Pusher

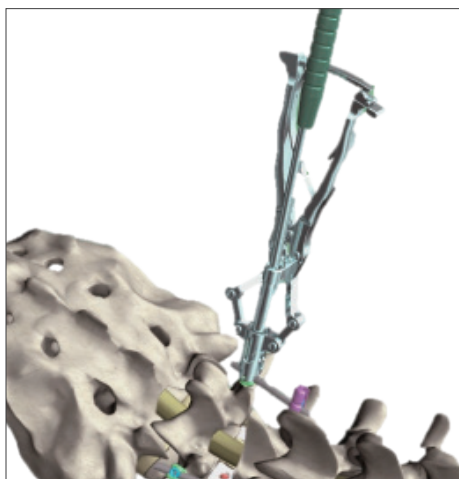


Figure 8

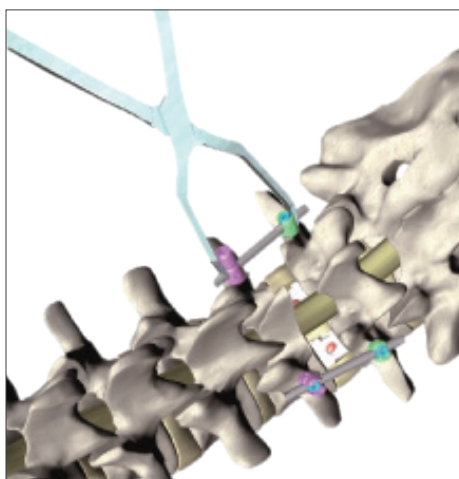


Figure 9

07 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. (Fig. 8).

08 Distraction and Compression

Distraction and compression is achieved through 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. (Fig. 9).



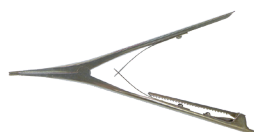
407-1301

Set Screw Holder



407-1403

Rod Introducer



407-0902

Angled Distractor



407-0901

Angled Compressor

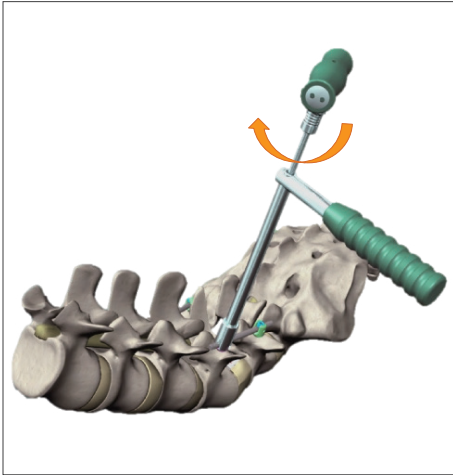


Figure 10

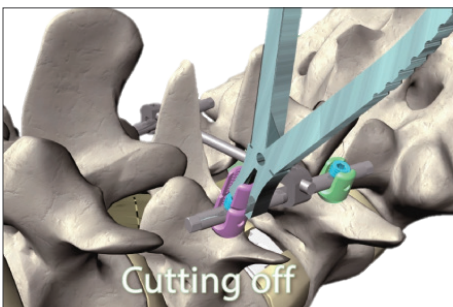


Figure 11

09 Final Tightening

Assemble the **4mm Hex Screw Driver (407-3310)** 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. (Fig. 10).

10 Removal of Reduction Tabs

The **Long Arm Cutting Forceps (407-2102)** is used to remove the remaining tab of the Long-Arm screws. (Fig. 11).



407-3310

4mm Hex Screw Driver



407-3402

Anti-Torque Wrench



407-2102

Long Arm
Cutting Forceps

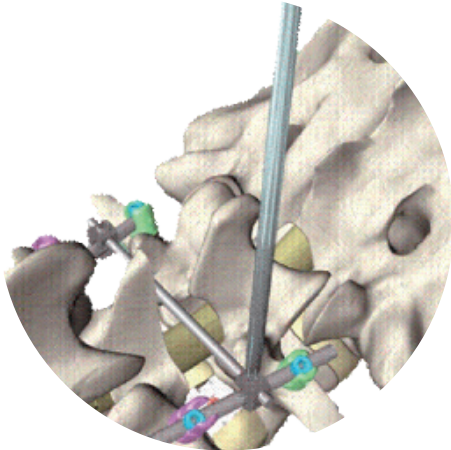


Figure 12

11 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)**. (Fig. 12).

12 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.



412-3101

T20 Screw Wrench



407-3309

4mm Hex Screw Driver



406-0101

T-Handle



407-3302

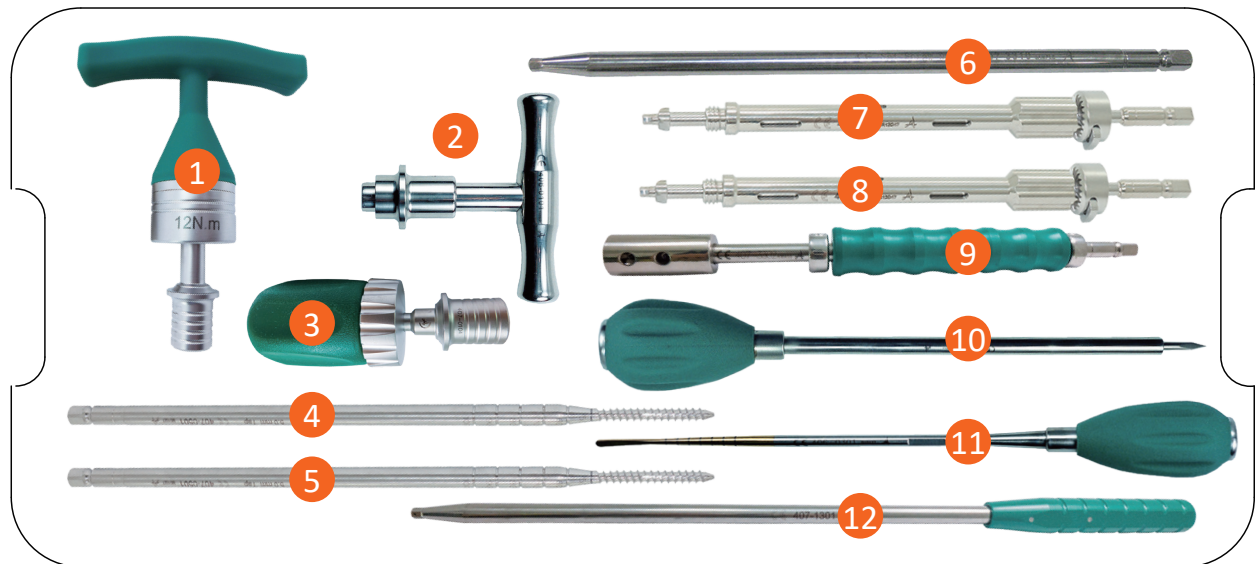
Top Loading Screw Driver



407-3313

3.5mm
Polyaxial Screw Driver

Instrument Set



Instrument Tray 1

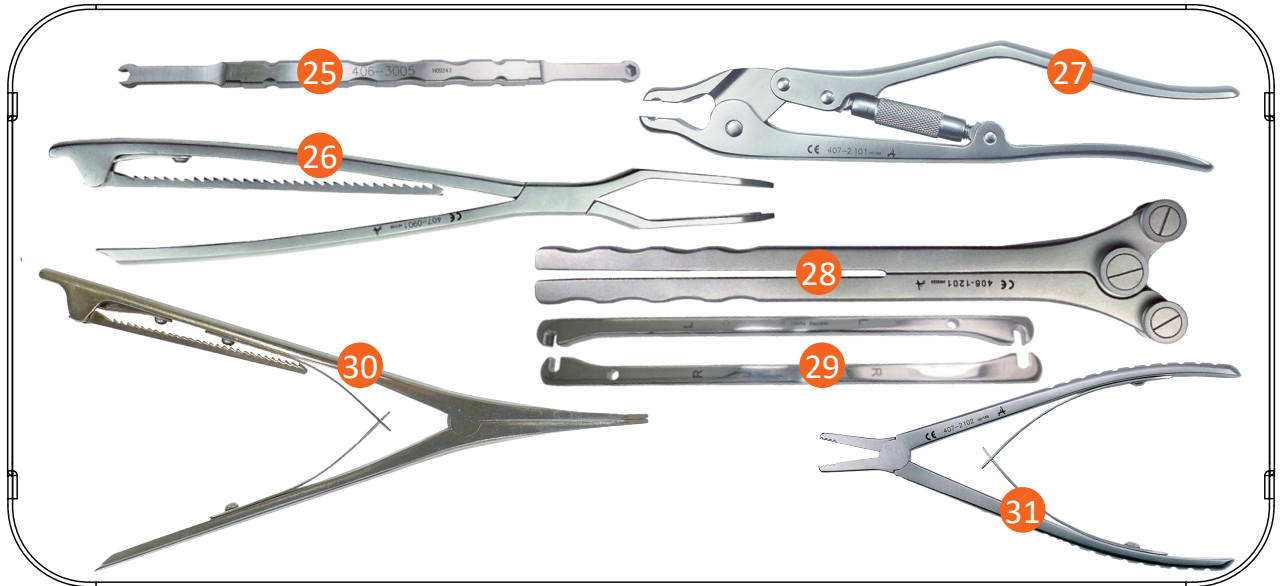
Cat.No.	Description	Q'nty
① 407-1002	Torque Limiting T-Handle	1
② 406-0101	T-Handle	1
③ 407-0104	Ball Handle, Ratchet	*
④ 407-0501	5mm Tap	1
⑤ 407-0502	6mm Tap	1
⑥ 407-3310	4mm Hex Screw Driver	1
⑦ 407-3313	3.5mm Polyaxial Screw Driver	2
⑧ 407-3316	3.5mm Poly Longarm Driver	2
⑨ 407-3302	Top Loading Screw Driver	2
⑩ 406-0201	Awl (With Stop)	1
⑪ 406-0301	Probe	1
⑫ 407-1301	Set Screw Holder	2

* Option



Instrument Tray 2

Cat.No.	Description	Q'nty
13 406-3114	4mm Guide Pin	4
14 407-3402	Anti-Torque Wrench	1
15 406-3104	4mm Guide Pin	4
16 407-2902	Rod Template 300mm	1
17 407-2901	Rod Template 150mm	1
18 406-0836	3.5mm Adjust Driver	1
19 407-3309	4mm Hex Screw Driver	1
20 406-0401	Sensor	1
21 412-3101	T20 Screw Wrench	1
22 406-2601	Rod Pusher	1
23 407-1403	Rod Introducer	1
24 406-1301	Rod Holder	1



Instrument Tray 3

Cat.No.	Description	Q'nty
25 406-3005	5mm Rotator Bar	2
26 407-0901	Angled Compressor	1
27 407-2101	Rod Clamp	1
28 406-1201	Rod Bender (french bender)	1
29 406-1203	Insitu Bender	1
30 407-0902	Angled Distractor	1
31 407-2102	Long Arm Cutting Forceps	1

Instruments

Cat.No.	Description	
20141-022	SmartLoc Block	
406-0101	T-Handle	
406-0201	Awl (With Stop)	
406-0301	Probe	
406-0401	Sensor	
406-0836	3.5mm Adjust Driver	
406-1201	Rod Bender (french bender)	
406-1203	Insitu Bender	
406-1301	Rod Holder	
406-2601	Rod Pusher	
406-3005	5mm Rotator Bar	
406-3104	4mm Guide Pin	

Cat.No.	Description	
406-3114	4mm Guide Pin	
407-0104	Ball Handle, Ratchet*	
407-0501 407-0502	5mm Tap 6mm Tap	
407-0901	Angled Compressor	
407-0902	Angled Distractor	
407-1002	Torque Limiting T-Handle	
407-1301	Set Screw Holder	
407-1403	Rod Introducer	
407-2101	Rod Clamp	
407-2102	Long Arm Cutting Forceps	
407-2901	Rod Template 150mm	
407-2902	Rod Template 300mm	

* Optional

Cat.No.	Description	
407-3302	Top Loading Screw Driver	
407-3309	4mm Hex Screw Driver	
407-3310	4mm Hex Screw Driver	
407-3313	3.5mm Polyaxial Screw Driver	
407-3316	3.5mm Poly Longarm Driver	
407-3402	Anti-Torque Wrench	
412-3101	T20 Screw Wrench	
99902-021	SmartLoc Product Case, Metal Lid	
99902-022	SmartLoc Instrument Case, Metal Lid	
99904-021	SmartLoc Product Case, Plasty Lid*	
99904-022	SmartLoc Instrument Case, Plasty Lid*	

* Optional

Sterilization :

The implants and instruments are delivered non sterile; they need to be cleaned and sterilized before operation. It is 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, dry for 30 minutes.
- Steam Wrapped Dynamic-Air-Removal (Pre-vacuum) at 132 °C/270 °F for 4 minutes, dry 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/>

NOTE



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