

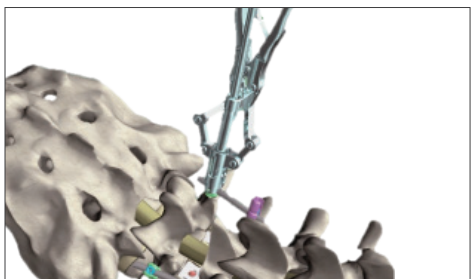
SmartLoc[®] Spinal Fixation System



+ Characteristics

- Top-Loading System
- Three points fixation monoaxial & polyaxial screws

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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

Sterilization

The SmartLoc Spinal Fixation System implants are delivered non sterile. Before use, the implants are to be removed from the package, cleaned and sterilized. Implants are recommended to be steam sterilized by the hospital using the 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.

System Components

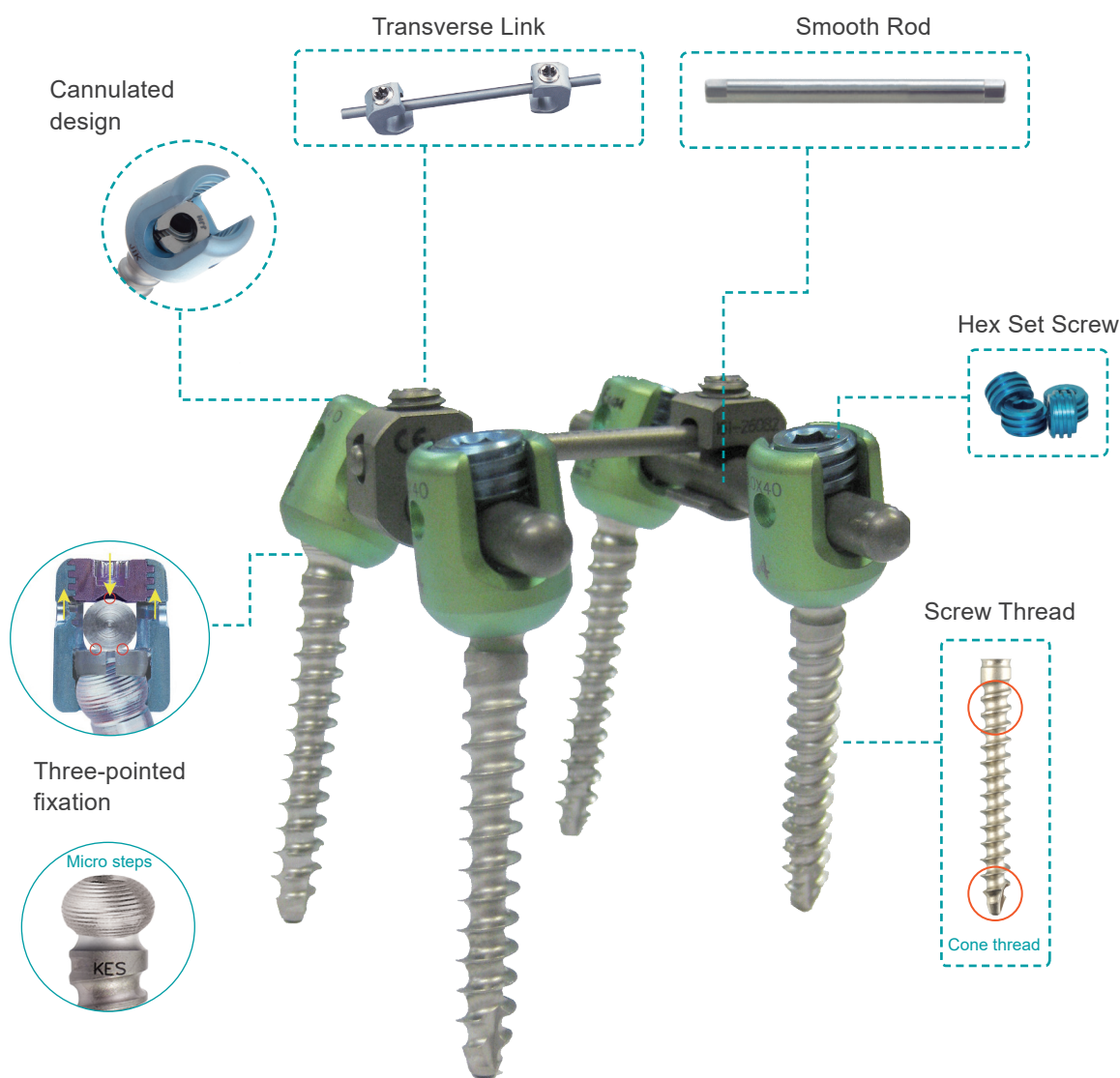
Components of the SmartLoc Spinal Fixation System afford a high extent of versatility and simplicity in the course of spine surgery.

1. available in a variety of specifications & dimensions for the needs of comprehensive spinal surgery requirements.
2. Periphery components such as star set screws, connector blocks are available in complete range to accommodate key components for easy assembly to the users.
3. All components are documented in product catalog with full details for user's preference purpose.

Thus, it is not the intention of this manual to contain such information.



System Overview



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)

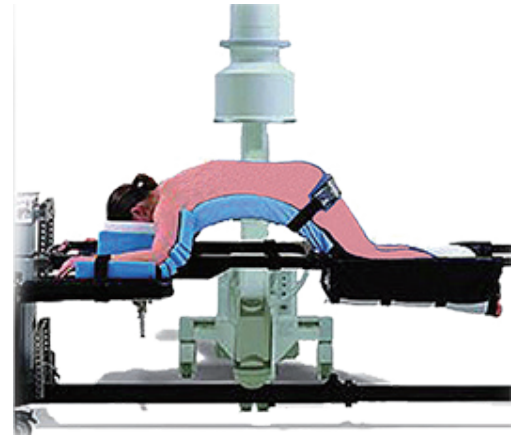


Figure 1

○ 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.

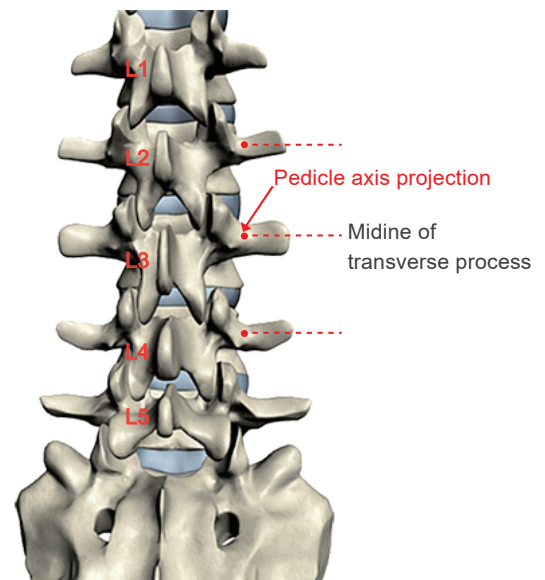
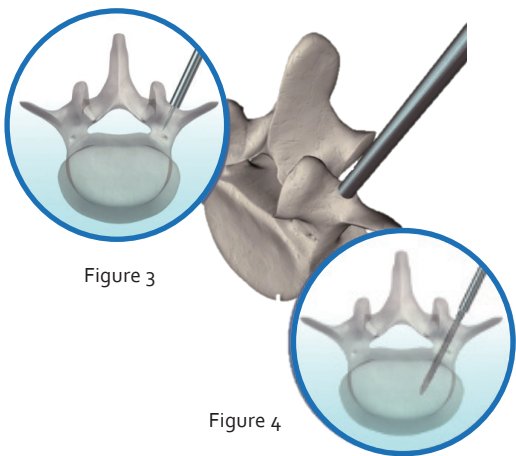


Figure 2

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.

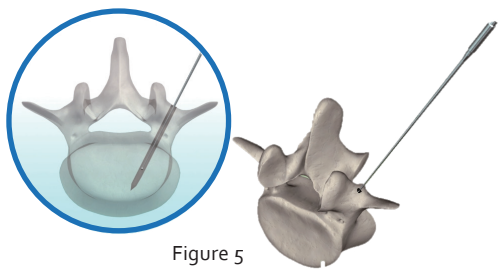


Pedicle Preparation

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



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)



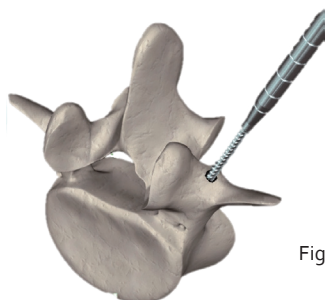


Figure 6

For convenience, the **T-Handle (406-0101)** is attached to instrument.

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

Choose the appropriate **Tap (407-0501~407-0506)** to prepare the pedicle canal. (Figure 6).

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

*Option



○ Inserting Screw

The appropriate screw is mounted and fastened onto the **Screw Driver (407-3302~407-3316)**.

(Figure 7)

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

407-3302



407-3313



407-3316



Figure 7

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

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 (407-3306)** .



406-0101

T-Handle



407-3306

3mm Hex Screw Driver



Figure 8

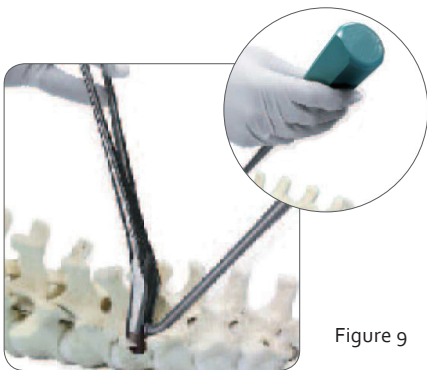


Figure 9

Inserting Hook

The hooks are attached to the strategic vertebrae, pre-operatively chosen by the surgeon. They can be isolated or associated to make a clamp. The appropriate **Hook Starter (197-0702, 197-0703)** is used to prepare the hook site. The desired hook is taken with the **Hook Driver (407-3201)** (Figure 8). **Use Hook Clamp (407-2103)** to help the hooks implants into the prepared space. In case of necessity, the **Hook Impactor (407-3001)** may ease the hook insertion (Figure 9).



Offset Hook

Cat.No.

156-37092 (Left offset Hook)
156-37112 (Right offset Hook)
156-27092
156-27112



Lamina Hook

Cat.No.

156-05072
156-05092
156-07072
156-07092



Pedicle Hook

Cat.No.

156-18092
156-18072
156-18052



197-0702

Laminar Hook Starter



197-0703

Pedicle Hook Starter



407-3201

Hook Driver



407-2103

Hook Clamp



407-3001

Hook Impactor

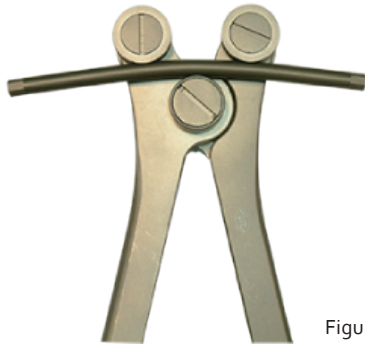


Figure 10

○ 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 10)

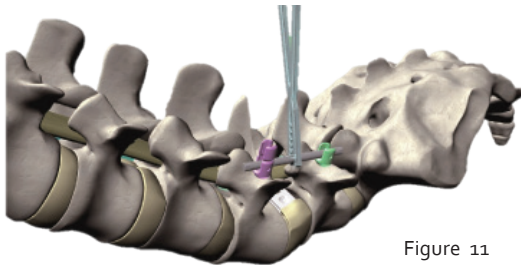


Figure 11

○ Rod Reduction

The **Rod Holder (406-1301)** is used to hold the rod and introduce it into the head of the screw. (Figure 11)

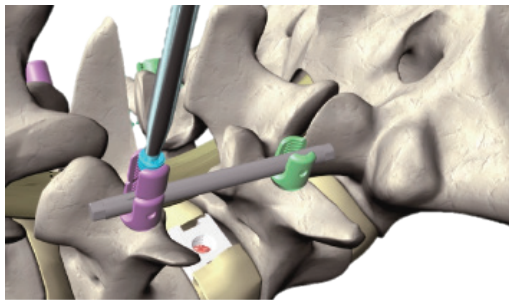


Figure 12

○ 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 12)



406-1201

Rod Bender



406-1301

Rod Holder



407-1301

Set Screw Holder



407-3309

4mm Hex Screw Driver



406-2601

Rod Pusher

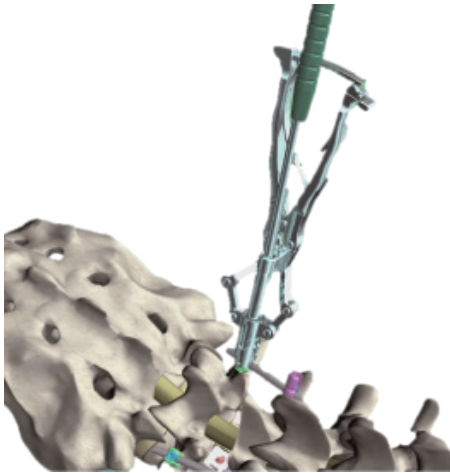


Figure 13

○ Rod Introducer

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

Rod Introducer can persuade 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 13)

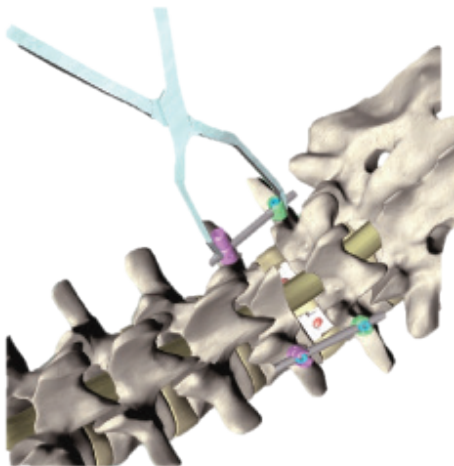


Figure 14

○ 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. (Figure 14)



407-1403

Rod Introducer



407-0902

Angled Distractor



407-0901

Angled Compressor

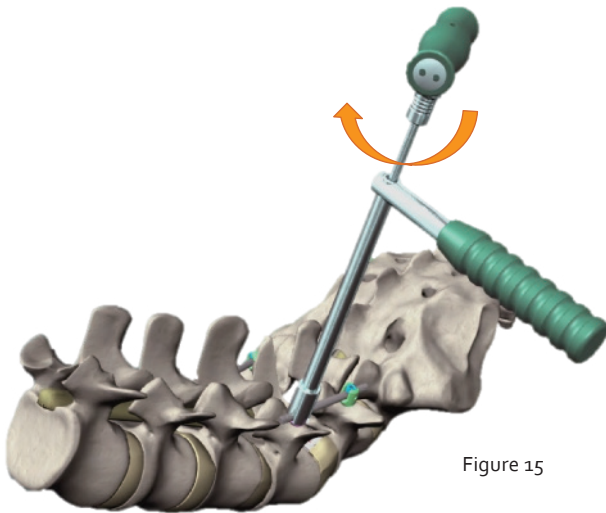


Figure 15

○ Final Tightening

Assemble the **4mm Hex Screw Driver (407-3310)** and **Torque Limiting T-Handle (407-1002)** 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. (Figure 15)

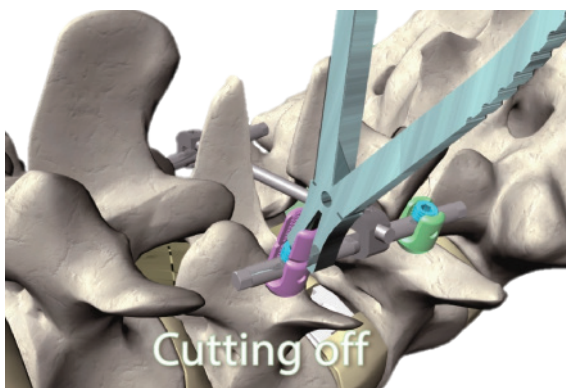


Figure 16

○ Removal of Reduction Tabs

The **Long Arm Cutting Forceps (407-2102)** is used to remove the remaining tab of the Long-Arm screws. (Figure 16)



407-3310

4mm Hex Screw Driver



407-1002

Torque Limiting T-Handle



407-3402

Anti-Torque Wrench



407-2102

Long Arm Cutting Forceps

○ 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)**. (Figure 17)

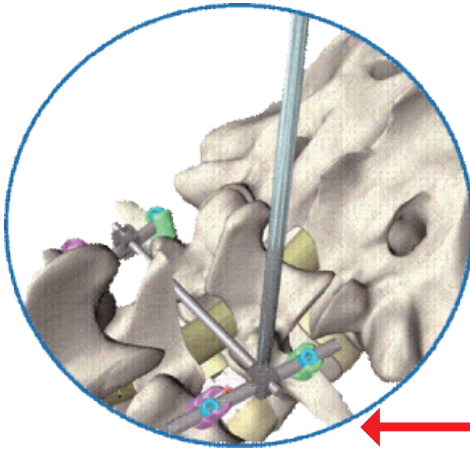


Figure 17



○ 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



407-3302

4mm Hex Screw Driver



407-3313

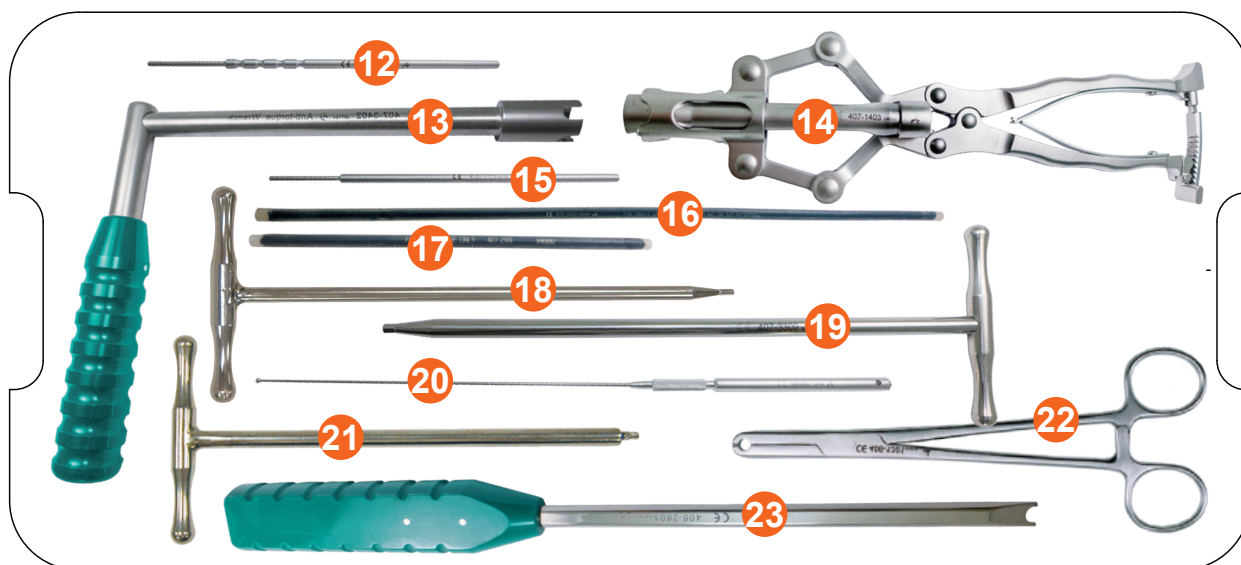
3.5mm
Polyaxial Screw Driver

Instrument Set



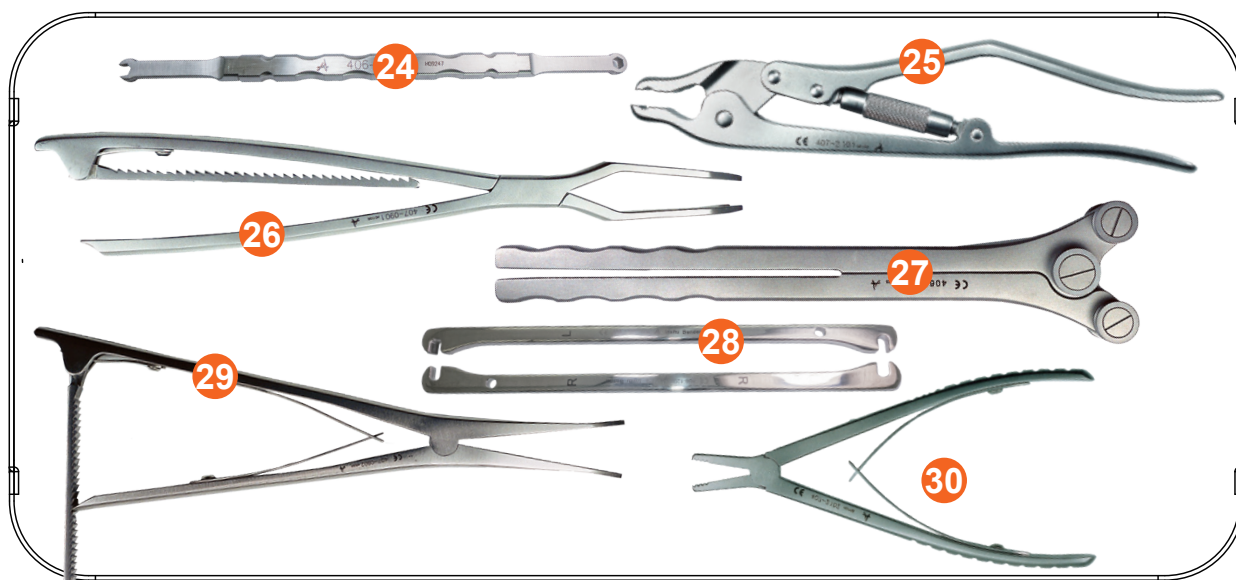
Instrument Tray 1

Cat.No.	Description	Q'nty
① 406-0101	T-Handle	1
② 407-1002	Torque Limiting T-Handle	1
③ 406-0505	5 mm Tap	1
④ 406-0506	6 mm Tap	1
⑤ 407-3310	4mm Hex Screw Driver	1
⑥ 407-3301	Polyaxial Screw Driver	2
⑦ 407-3316	Polyaxial Screw Driver	2
⑧ 407-3302	Top Loading Screw Driver	2
⑨ 406-0201	Awl (With Stop)	1
⑩ 406-0301	Probe	1
⑪ 407-1301	Set Screw Holder	2



Instrument Tray 2

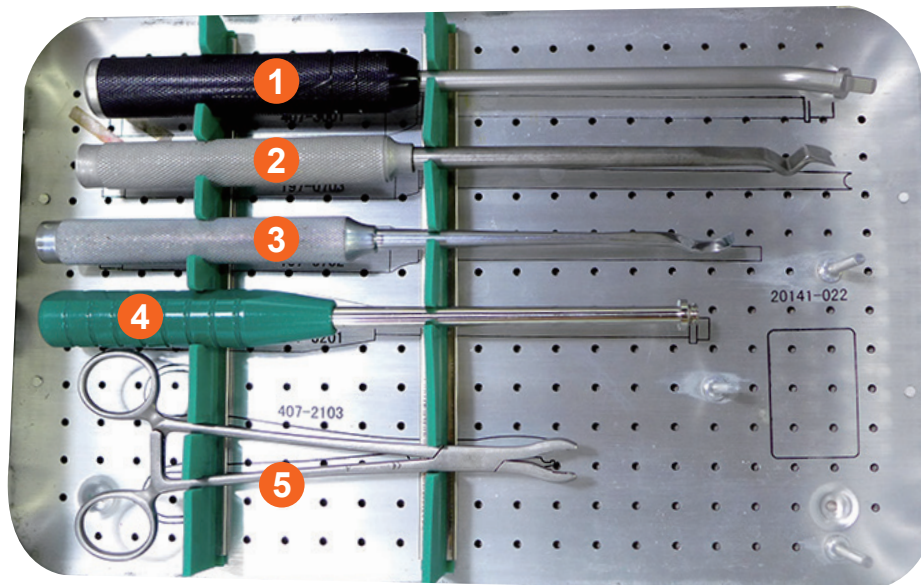
Cat.No.	Description	Q'nty
12 406-3114	4mm Guide Pin	4
13 407-3402	Counter Torque	1
14 407-1403	Rod Introducer	1
15 406-3104	4mm Guide Pin	4
16 407-2902	Rod Template 300mm	1
17 407-2901	Rod Template 150mm	1
18 407-3306	3mm Hex Screw Driver	1
19 407-3309	4mm Hex Screw Driver	1
20 406-0401	Sensor	1
21 412-3101	T20 Screw Wrench	1
22 406-1301	Rod Holder	1
23 406-2601	Rod Pusher	1



Instrument Tray 3

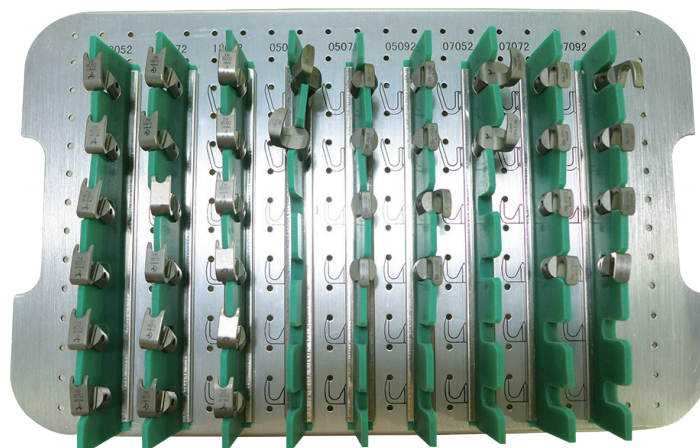
Cat.No.	Description	Q'nty
24 406-3005	5mm Rotator Bar	2
25 407-2101	Rod Clamp	1
26 407-0901	Angled Compressor	1
27 406-1201	Rod Bender (French Bender)	1
28 406-1203	Insitu Bender	1
29 407-0902	Angled Distractor	1
30 407-2102	Long Arm Cutting Forceps	1

Hook Instrument



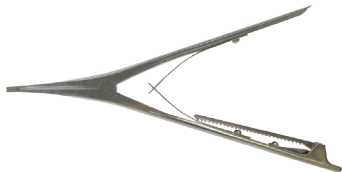
Cat.No.	Description	Q'nty
① 407-3201	Hook Impactor	1
② 197-0703	Pedicle Hook Starter	1
③ 197-0702	Laminar Hook Starter	1
④ 407-3001	Hook Impactor	1
⑤ 407-2103	Hook Clamp	1

Hook Implants



Instruments

Cat.No.	Description	
197-0703	Pedicle Hook Starter	
197-0702	Laminar Hook Starter	
406-0101	T-Handle	
406-0201	Awl (With Stop)	
406-0301	Probe	
406-0401	Sensor	
406-1201	Rod Bender (French Bender)	
406-1203	Insitu Bender	
406-1301	Rod Holder	
406-2601	Rod Pusher	
406-3005	5mm Rotator Bar	

Cat.No.	Description	
406-3104 406-3114	4mm Guide Pin	
407-0501 407-0502	5mm Tap 6mm Tap	
407-0505 407-0506	4mm Tap 7mm 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	

Cat.No.	Description	
407-2103	Hook Clamp	
407-2901	Rod Template 150mm	
407-2902	Rod Template 300mm	
407-3001	Hook Impactor	
407-3201	Hook Driver	
407-3302	Small Dilator	
407-3306	3mm Hex 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	

Cat.No.	Description	
412-3101	T20 Screw Wrench	
20141-022	SmartLoc Block	
99900-030	Hook Instrument / Product Case with 1 Tray	
99902-030	Smartloc Hook Implant/Instrument Case With, Plasty Lid	
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	

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, dry time for 30 minutes.

Steam Wrapped Dynamic-Air-Removal (Pre-vacuum) Cycle at 132 °C/ 270 °F for 4 minutes, dry time 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

NOTE



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