

SmartLoc[®] Ω

OMEGA

Spinal Fixation System



➤➤➤ *Advancing Spine Technology*



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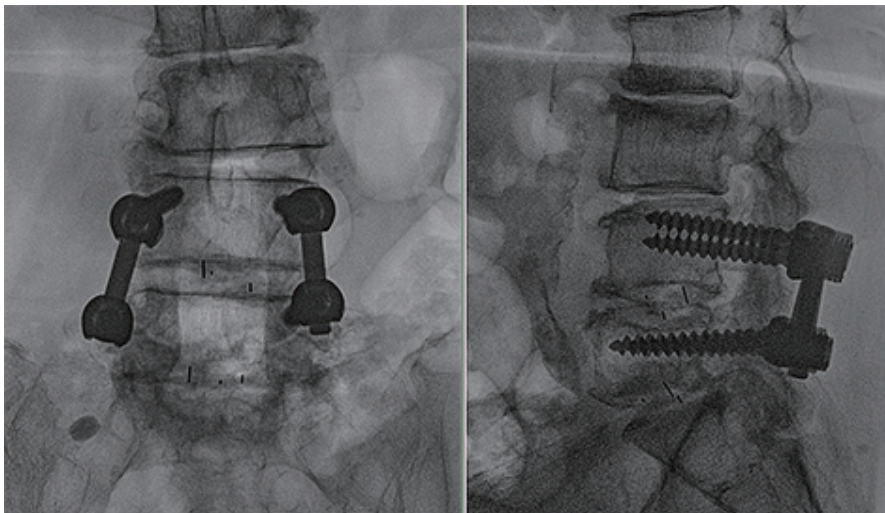
Indication

- 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



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. (Figure1)

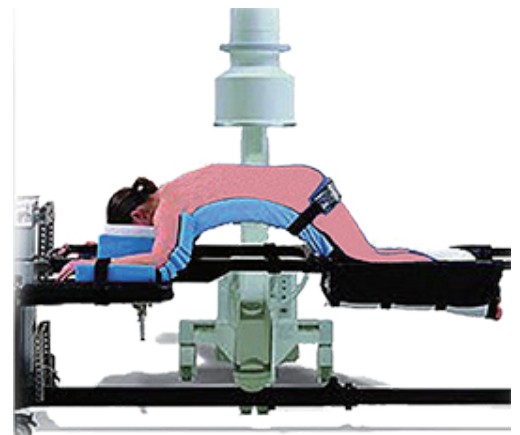


Figure 1

Locate the Pedicle Entry Points (Figure 2)

The use of the SmartLoc 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.

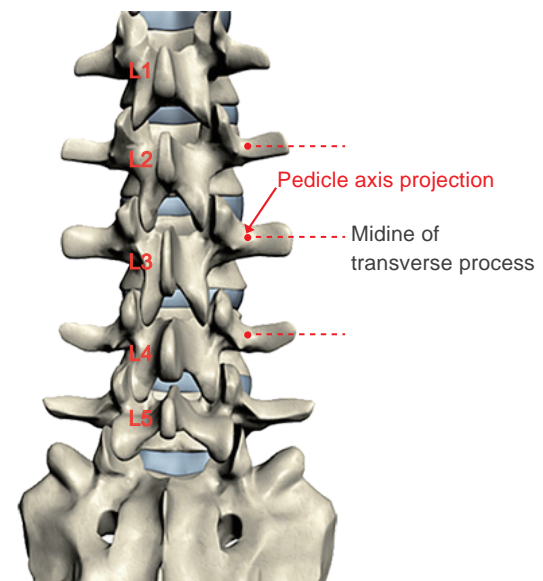


Figure 2

The entry point of sacral fixation located at inferior lateral aspect of the L5-S1 facet joint, converging toward the center of the 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.

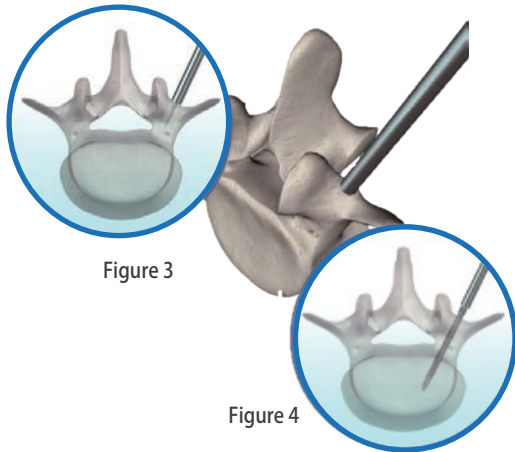


Figure 3

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

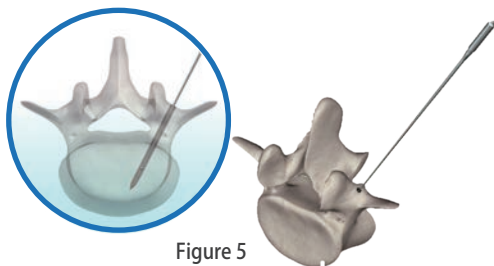


Figure 5

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)



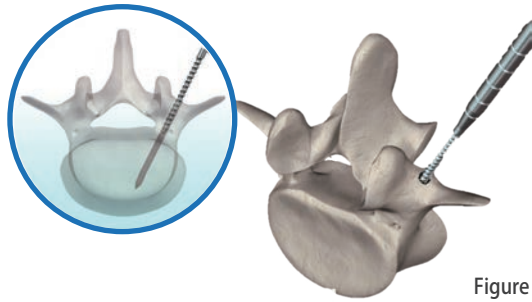


Figure 6

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



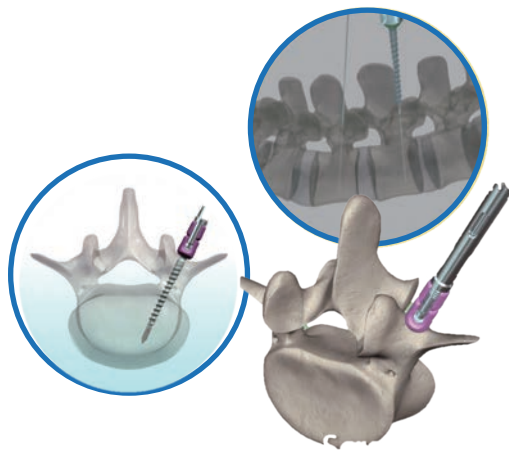


Figure 7

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. (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

About the bone cement augmentation materials are available for PMMA type or Calcium sulfate for injectable formula.

SmartLoc Omega system will pack with 4 pair of bone cement delivery kit in the instruments container.

The cement introducer at the end portion is design with a Morse taper to support the delivery force when engaged in feeding bone cement would be more easily. (Figure 8)



Figure 9

Mix the PMMA bone cement

Preload the bone cement into the Introducer (407-1404) in advance, each one can fill with 1.5 C.C.

After that mount to the screw and push the syringe for cement inject into the cannulated screw.

Finally take the Cement Pusher (407-2602) to push rest of the bone cement out of the introducer. (Figure 9 and 10)

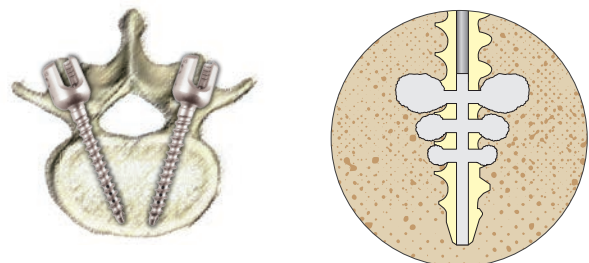


Figure 10

Note:

Make sure the pedicle screw reaches the target site before using the cement.

After the cement is injected, wait for a while to make sure it has become solid and will not leak.



1. Zhan, Yi, et al. "Risk factors for cement leakage after vertebroplasty or kyphoplasty: a meta-analysis of published evidence." *World neurosurgery* 101 (2017): 633-642.

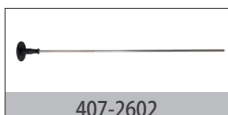




Figure 11

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 11)

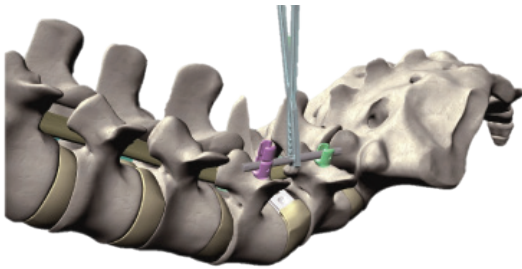


Figure 12

Rod Introduction

The Rod Holder (406-1301) is used to hold the rod and introduce it into the head of the screw. (Figure 12)

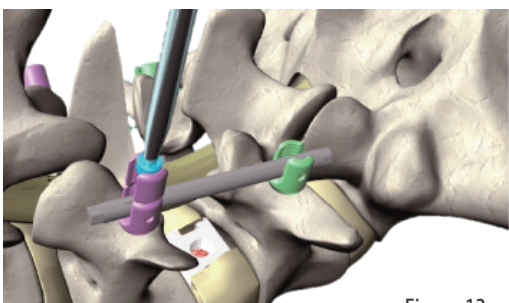
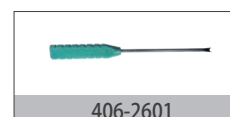


Figure 13

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 13)



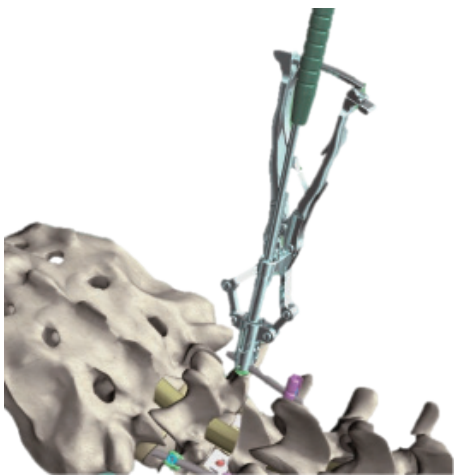


Figure 14

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 14)

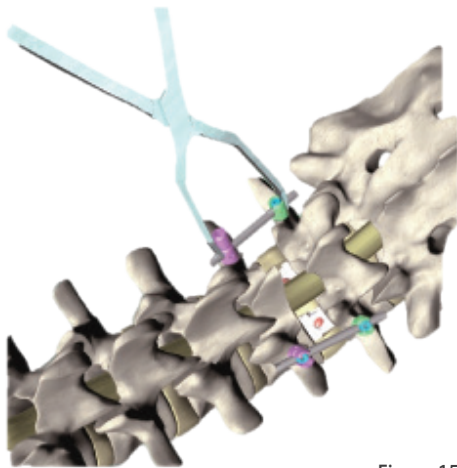
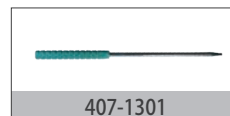
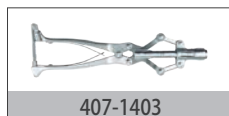
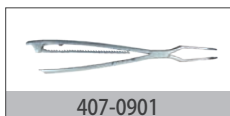


Figure 15

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 15)



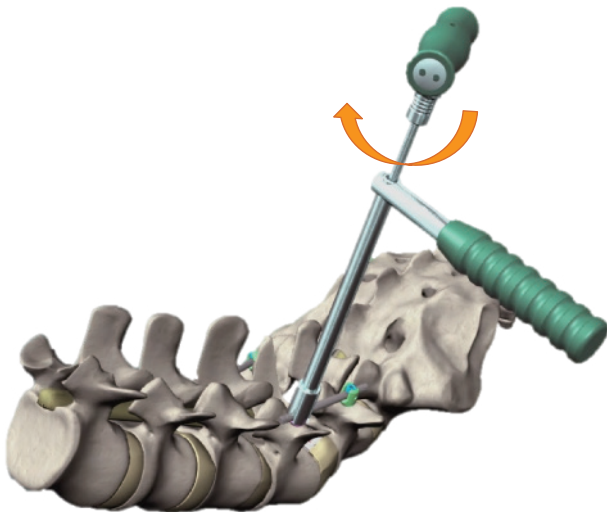


Figure 16

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. (Figure16)

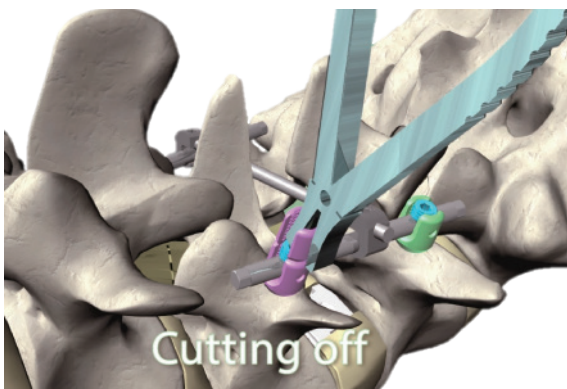
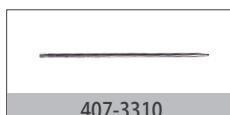


Figure 17

Removal of Reduction Tabs

The Long Arm Cutting Forceps(407-2102) is used to remove the remaining tab of the Long-Arm screws. (Figure 17)



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). (Figure18)

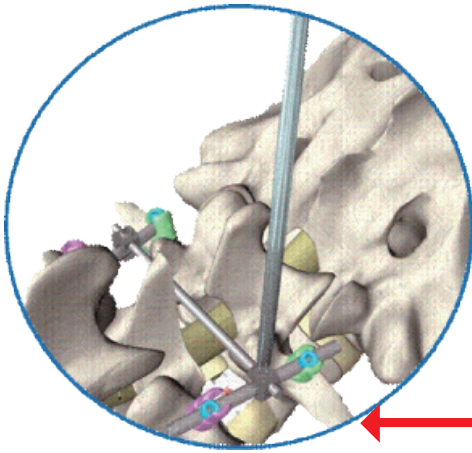
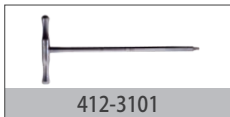


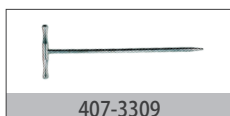
Figure 18



412-3101

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.



407-3309



406-0836



407-3302



407-3313

Instruments



406-0101

T-Handle



406-0301

Probe



407-0501
407-0502

5mm Tap
6mm Tap



406-1301

Rod Holder



406-3005

5mm Rotator Bar



407-3310

4mm Hex Screw Driver



406-0201

Awl (With Stop)



406-0401

Sensor



407-0505
407-0506

4mm Tap *Option
7mm Tap *Option



406-2601

Rod Pusher



406-3104
406-3114

4mm Guide Pin



407-0901

Angled Compressor



407-0902

Angled Distractor



407-2101

Rod Clamp



407-3402

Anti-Torque Wrench



407-3316

3.5mm Poly Longarm Driver



406-0836

3.5mm Adjust Driver



407-1301

Set Screw Holder



407-2102

Long Arm Cutting Forceps



407-2901

Rod Template
150mm



407-3313

3.5mm Polyaxial
Screw Driver



407-3302

Top Loading
Screw Driver



412-3101

T20 Screw Wrench



407-3309

4mm Hex
Screw Driver



406-1201

Rod Bender
(French Bender)



407-1403

Rod Introducer



407-2902

Rod Template
300mm



406-1203

Insitu Bender



407-1001

Torque Limiting
T-Handle



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



407-1105
407-1106
407-1107

Guide Wire, Ø1.5×500mm *Option
Guide Wire, Ø1.5×450mm
Guide Wire, Ø1.0×450mm *Option



407-1404

Introducer



407-2602

Cement Pusher



99901-022

Cannulated SmartLoc System



99905-022

Cannulated SmartLoc System, 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.

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/>

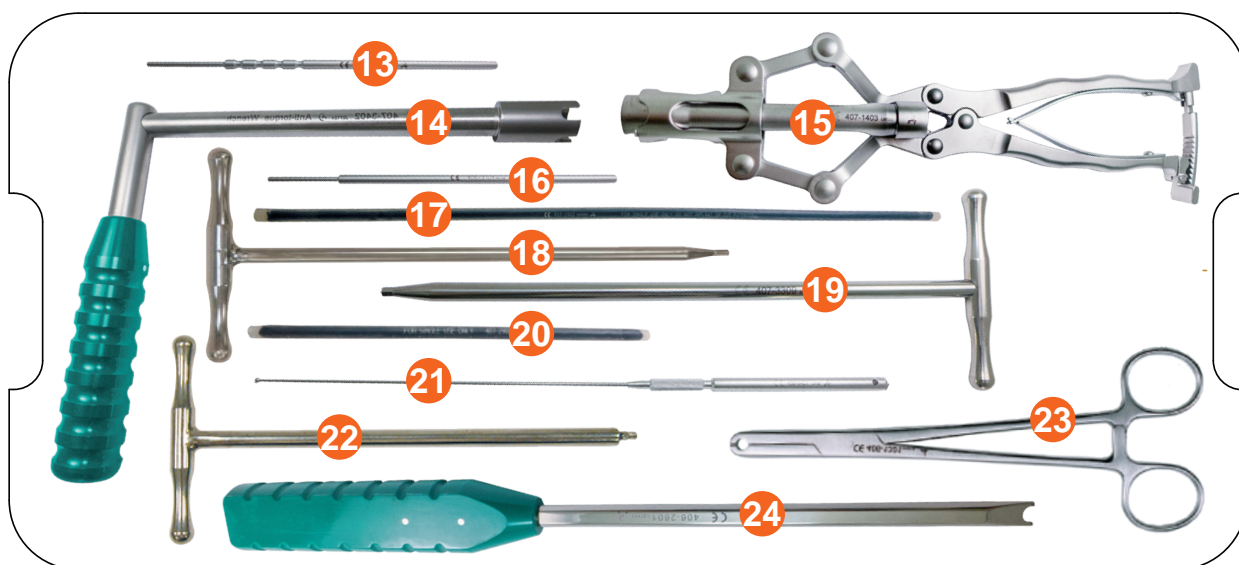
Instrument Set



Instrument Tray 1

Cat.No.	Description	Q'nty
① 406-0101	T-Handle	1
② 407-1001	Torque Limiting T-Handle	1
③ 407-0104	Ball Handle, Ratchet	*
④ 407-0503	5 mm Cannulated Tap	1
⑤ 407-0504	6 mm Cannulated Tap	1
⑥ 407-3310	4mm Hex Screw Driver	1
⑦ 407-3314	Cannulated Poly Screw Driver	2
⑧ 407-3317	Cannulated Poly Longarm Driver	2
⑨ 406-0201	Awl (With Stop)	1
⑩ 406-0301	Probe	1
⑪ 407-1106	Guide Wire, Ø1.5×500mm	*
⑫ 407-1301	Set Screw Holder	2

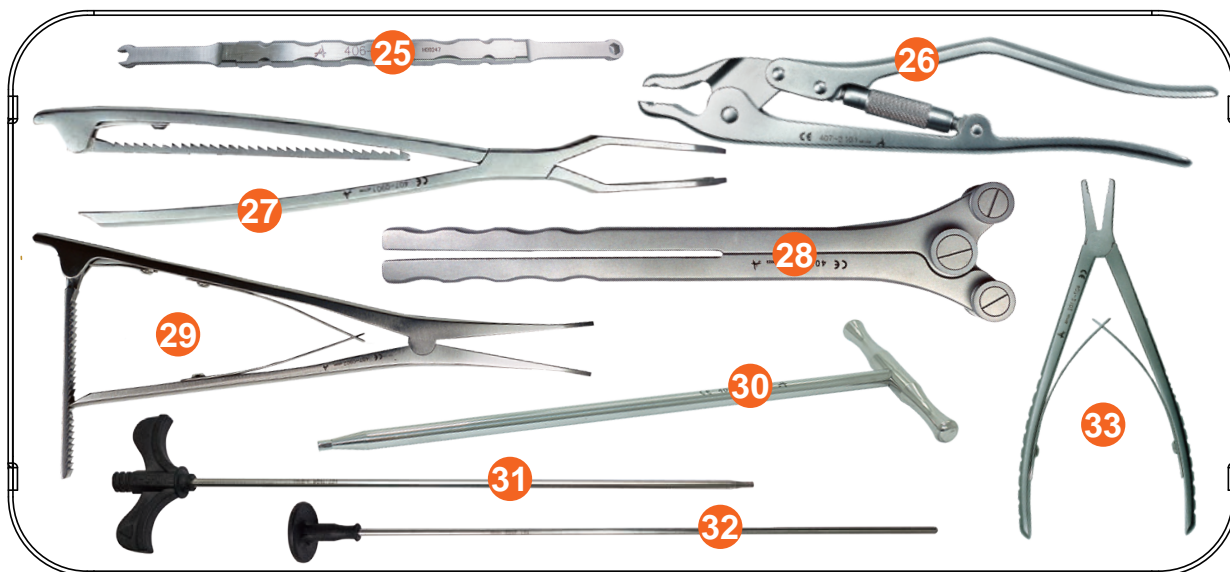
*Option



Instrument Tray 2

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

*Option



Instrument Tray 3

Cat.No.	Description	Q'nty
25 406-3005	5mm Rotator Bar	2
26 407-2101	Rod Clamp	1
27 407-0901	Angled Compressor	1
28 406-1201	Rod Bender (french bender)	1
29 407-0902	Angled Distractor	1
30 407-3315	3.5mm Cannulated Adjust Driver	*
31 407-1404	Introducer	4
32 407-2602	Cement Pusher	4
33 407-2102	Long Arm Cutting Forceps	1

*Option

Implants

Polyaxial Cannulated Screw

Cat.No.	Description
134-5535EN	Polyaxial Cannulated Screw Ø5.5mm x L35mm
134-5540EN	Polyaxial Cannulated Screw Ø5.5mm x L40mm
134-5545EN	Polyaxial Cannulated Screw Ø5.5mm x L45mm
134-6035EN	Polyaxial Cannulated Screw Ø6.0mm x L35mm
134-6040EN	Polyaxial Cannulated Screw Ø6.0mm x L40mm
134-6045EN	Polyaxial Cannulated Screw Ø6.0mm x L45mm
134-6050EN	Polyaxial Cannulated Screw Ø6.0mm x L50mm
134-6535EN	Polyaxial Cannulated Screw Ø6.5mm x L35mm
134-6540EN	Polyaxial Cannulated Screw Ø6.5mm x L40mm
134-6545EN	Polyaxial Cannulated Screw Ø6.5mm x L45mm
134-6550EN	Polyaxial Cannulated Screw Ø6.5mm x L50mm
134-7035EN	Polyaxial Cannulated Screw Ø7.0mm x L35mm
134-7040EN	Polyaxial Cannulated Screw Ø7.0mm x L40mm
134-7045EN	Polyaxial Cannulated Screw Ø7.0mm x L45mm
134-7050EN	Polyaxial Cannulated Screw Ø7.0mm x L50mm



Polyaxial Cannulated Long-Arm Screw

Cat.No.	Description
139-5540EN	Polyaxial Cannulated Long-Arm Screw Ø5.5mm x L40mm
139-5545EN	Polyaxial Cannulated Long-Arm Screw Ø5.5mm x L45mm
139-6540EN	Polyaxial Cannulated Long-Arm Screw Ø6.5mm x L40mm
139-6545EN	Polyaxial Cannulated Long-Arm Screw Ø6.5mm x L45mm
139-6550EN	Polyaxial Cannulated Long-Arm Screw Ø6.5mm x L50mm
139-7040EN	Polyaxial Cannulated Long-Arm Screw Ø7.0mm x L40mm
139-7045EN	Polyaxial Cannulated Long-Arm Screw Ø7.0mm x L45mm



Smooth Rod

Cat.No.	Description
132-50402	Smooth Rod Ø5.5mm x L40mm
132-50502	Smooth Rod Ø5.5mm x L50mm
132-50602	Smooth Rod Ø5.5mm x L60mm
132-50702	Smooth Rod Ø5.5mm x L70mm
132-50802	Smooth Rod Ø5.5mm x L80mm
132-50902	Smooth Rod Ø5.5mm x L90mm
132-51002	Smooth Rod Ø5.5mm x L100mm
132-51102	Smooth Rod Ø5.5mm x L110mm



Transverse Link

Cat.No.	Description
161-26082	Transverse Link Ø6.0mm x L13.5mm



Hex Set Screw (colorful)

Cat.No.	Description
174-07028	Hex Set Screw (colorful) Ø9.0mm x L5.0mm





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