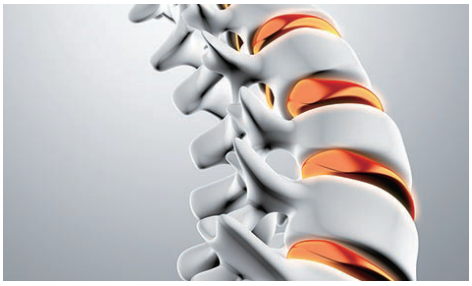
SmartLoc®

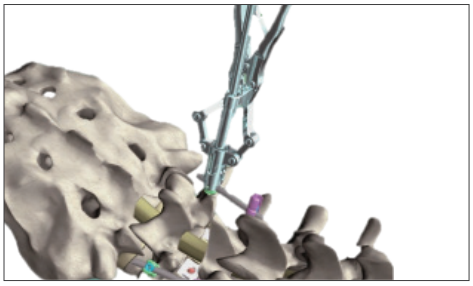
Spinal Fixation System

Advancing Spine Technology

A-SPINE

Contents





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

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:

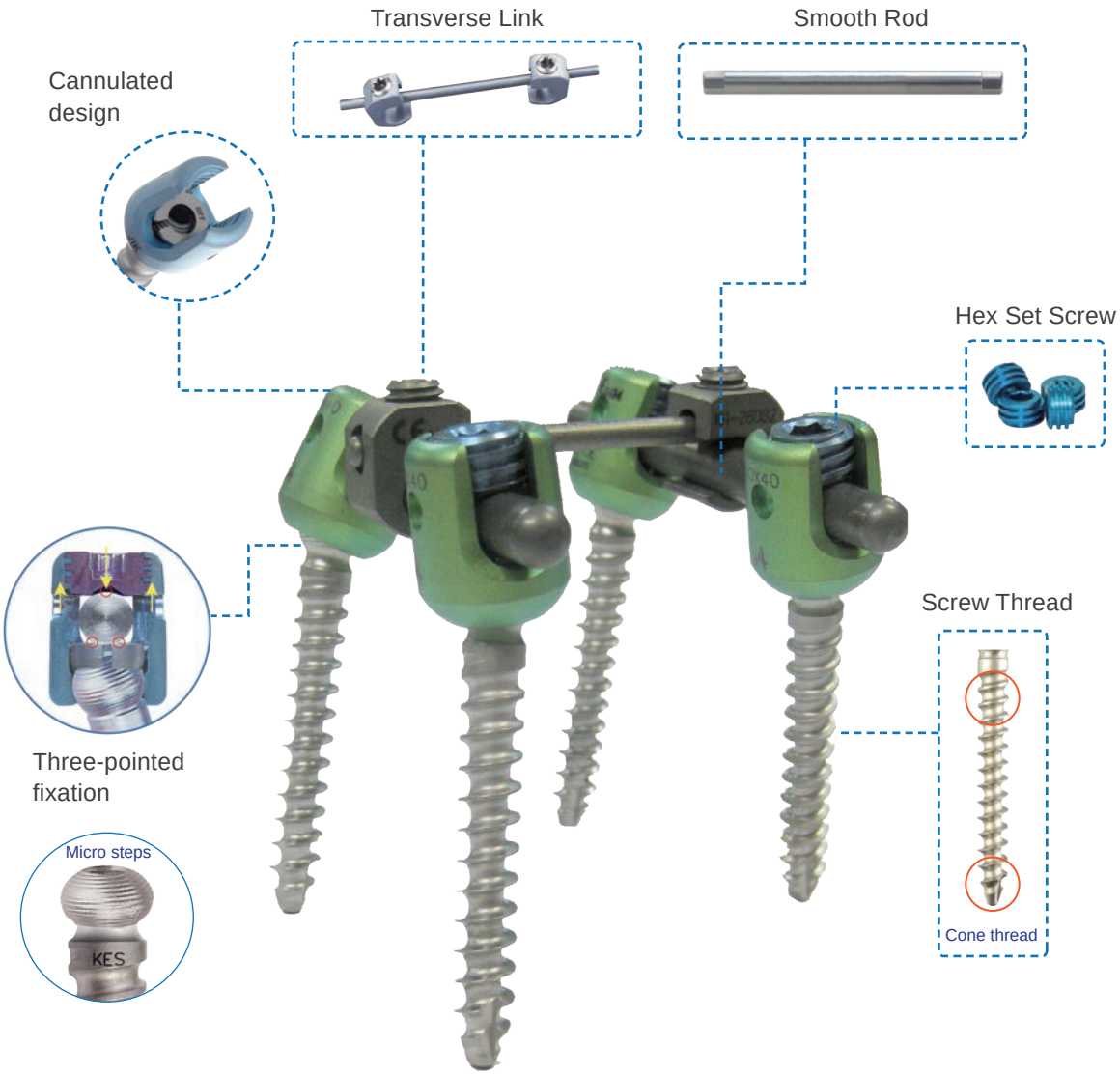
Steam Wrapped Gravity Cycle at 121 °C/250 °F for 30 minutes, Drying time 15 min

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-armto determine the axial direction of the pedicles, and to confirm that clear images of the affected levels are obtainable. The patient is subsequently prepped anddraped using standard technique. (Figure 1)

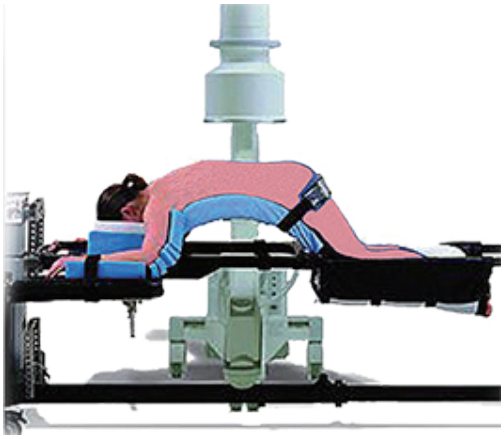


Figure 1

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 articulate 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.

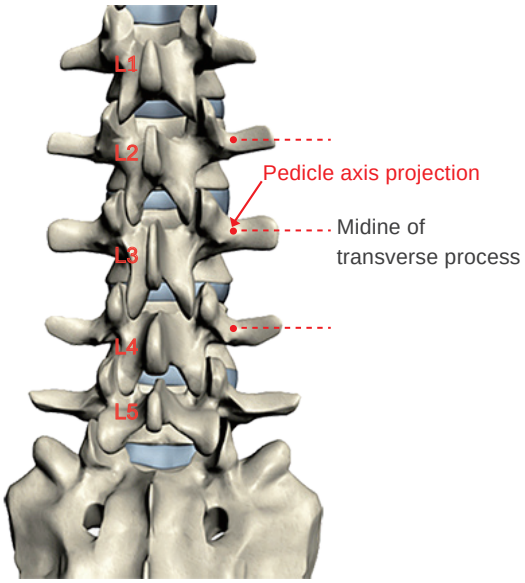


Figure 2

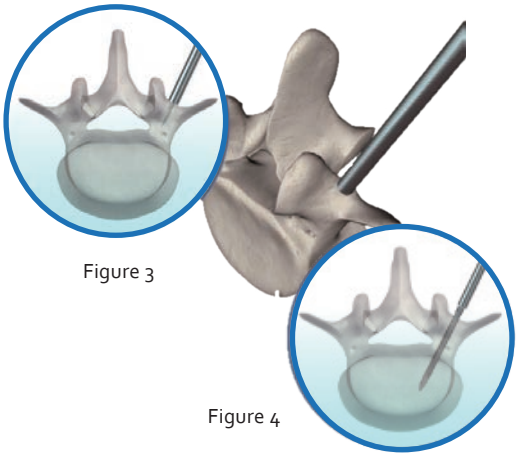


Figure 3

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 theassistance 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

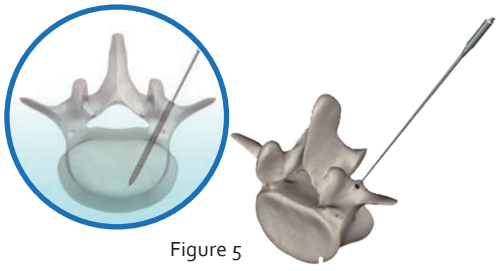


Figure 5

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	406-3104	406-3114	406-0401
Awl (With Stop)	Probe	4mm Guide Pin	4mm Guide Pin	Sensor

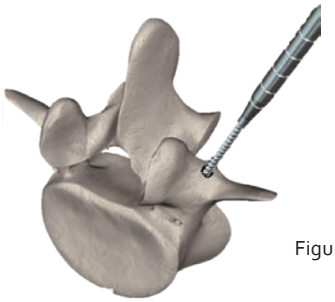


Figure 6

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 veterbral body, parallelling the superior end plates. The ***3.5mm Hex Screw Driver (407-3306)*** .

406-0101
T-Handle

407-3306
3mm Hex Screw Driver

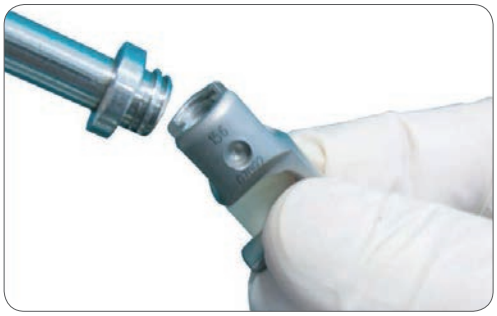


Figure 8

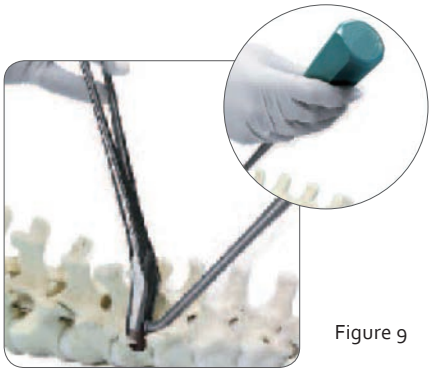


Figure 9

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 offest Hook)
156-37112 (Left offest Hook)
156-27092 (Right offest Hook)
156-27112 (Right offest Hook)

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

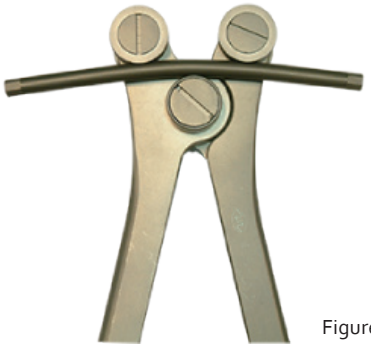


Figure 10

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)

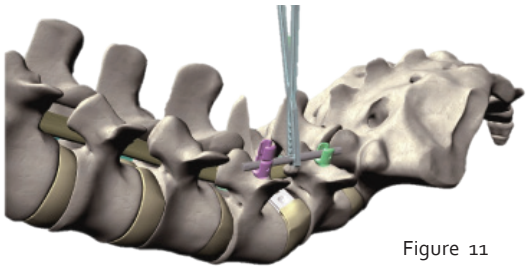


Figure 11

Rod Reduction

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

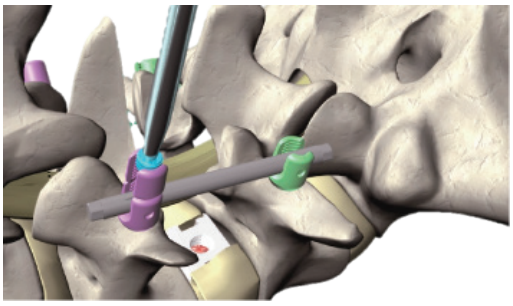


Figure 12

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

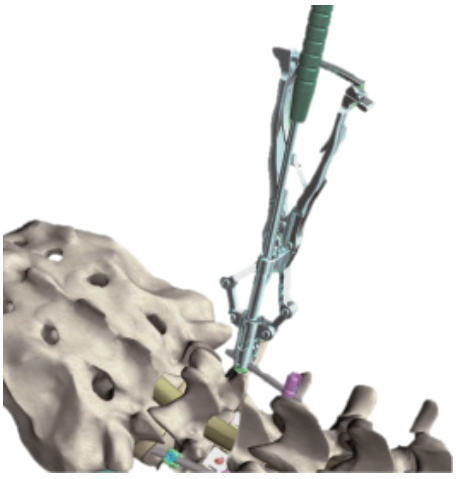


Figure 13

Rod Introducer

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

Rod Introducer can 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 13)

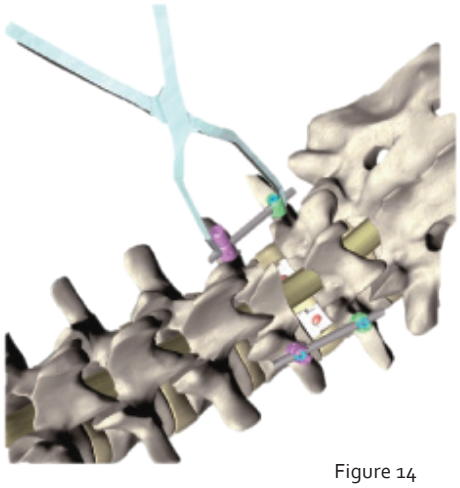


Figure 14

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 14)

407-1403
Rod Introducer

407-0902
Angled Distractor

407-0901
Angled Compressor

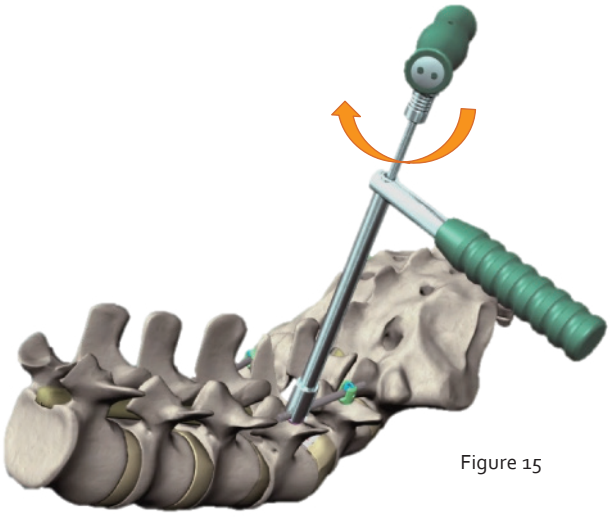


Figure 15

Final Tightening

Assemble the ***4mm Hex Screw Driver (407-3310)*** and ***Torque Limiting T-Handle(407-1001)*** 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. (Figure15)

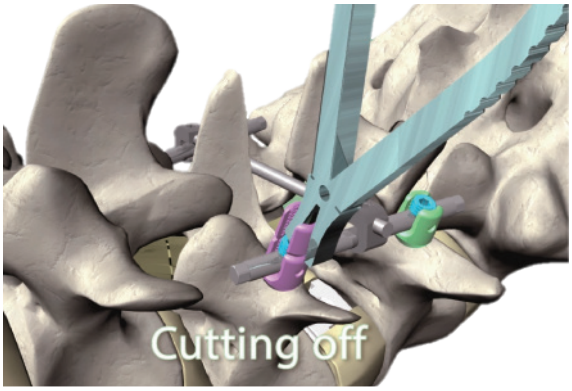


Figure 16

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

407-1001

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)

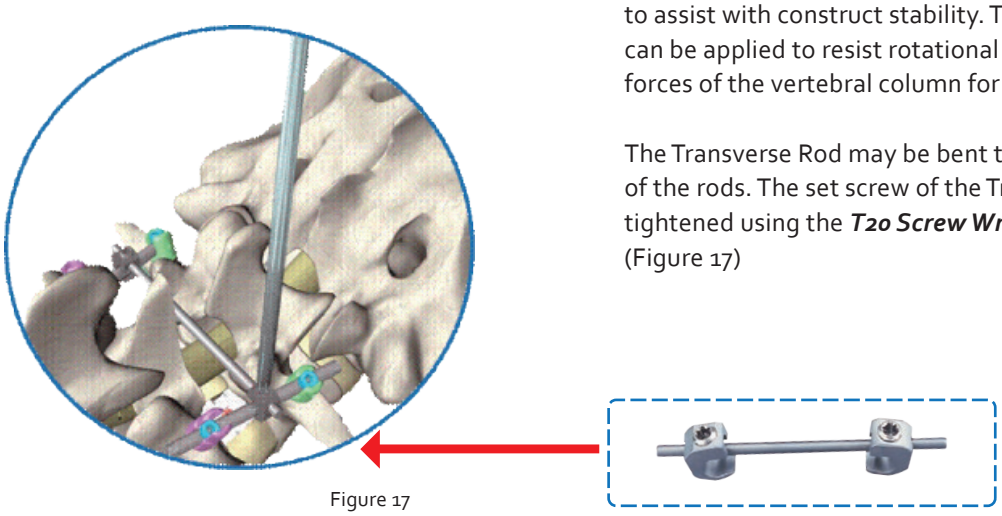


Figure 17

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

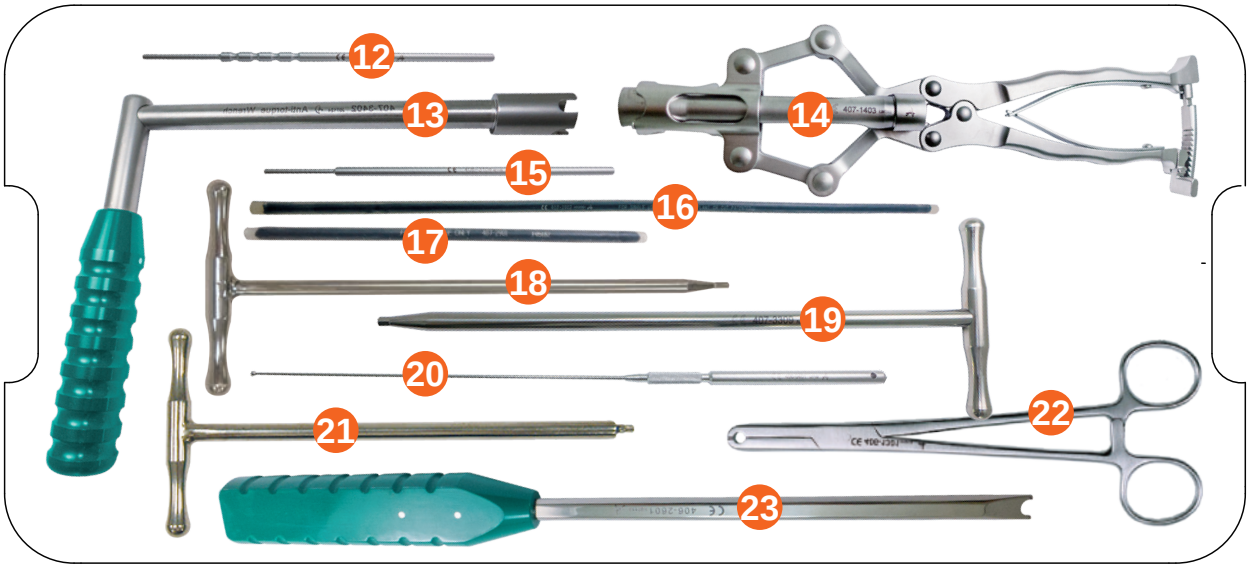
407-3313

3.5mm
Polyaxial Screw Driver

Instrument Set

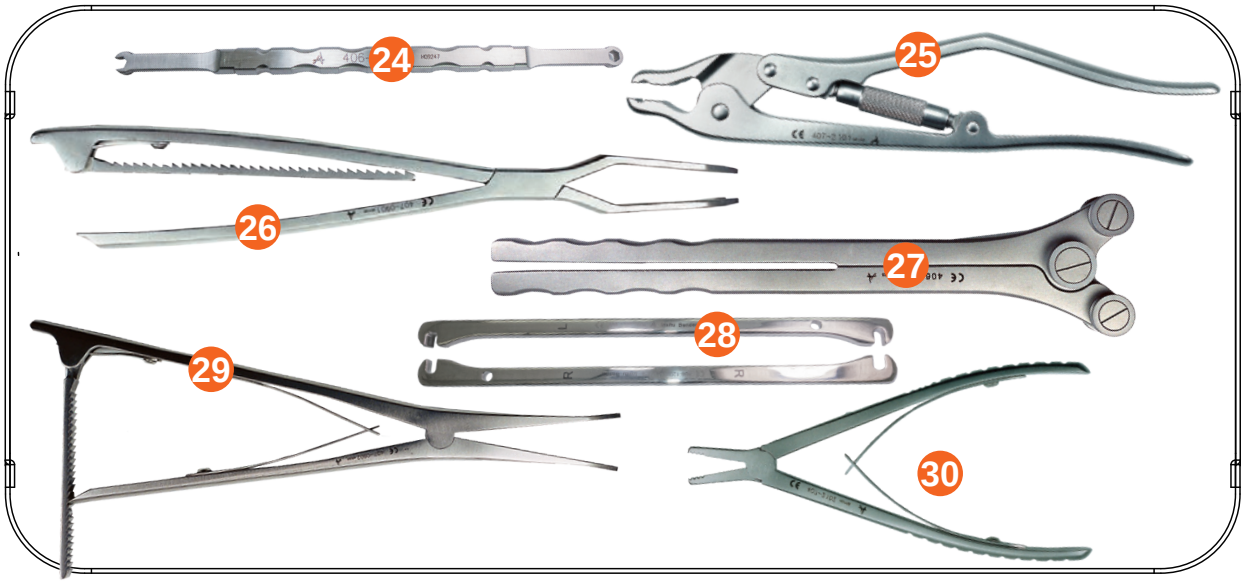
Instrument Tray 1

Cat.No.	Description	Q'nty
1 406-0101	T-Handle	1
2 407-1001	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

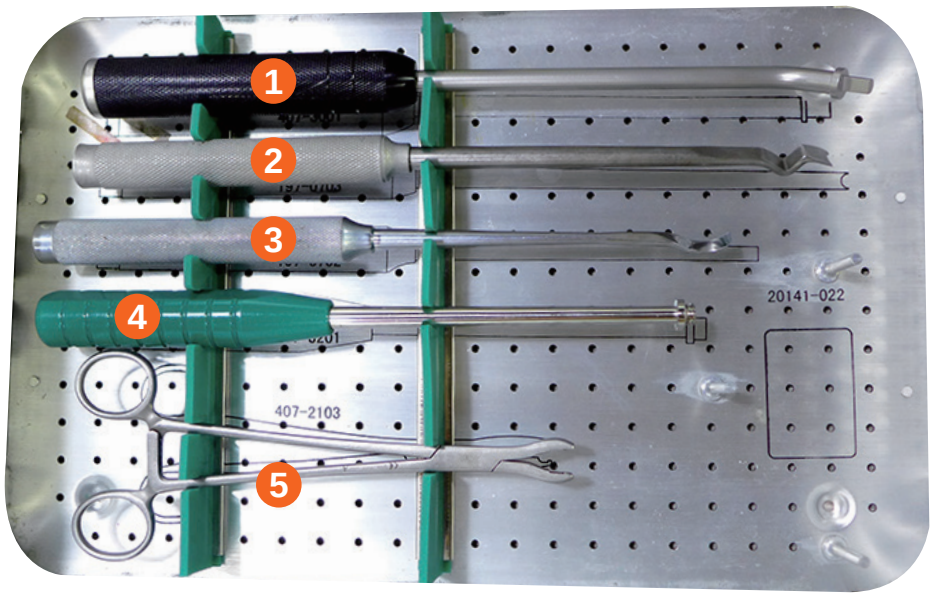
Cat.No.	Description	Q'nty
12 406-3114	4mm Guide Pin	4
13 407-3402	Counter Torque	1
14 407-1403	Rod Introducer	1
15 406-3104	4mm Guide Pin	4
16 407-2902	Rod Template 300mm	1
17 407-2901	Rod Template 150mm	1
18 407-3306	3mm Hex Screw Driver	1
19 407-3309	4mm Hex Screw Driver	1
20 406-0401	Sensor	1
21 412-3101	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	
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 7mm Tap	
406-1301	Rod Holder	
406-2601	Rod Pusher	
406-3005	5mm Rotator Bar	
406-3104 406-3114	4mm Guide Pin	
407-3310	4mm Hex Screw Driver	
407-0901	Angled Compressor	

Cat.No.	Description	
407-2101	Rod Clamp	
407-0902	Angled Distractor	
407-2102	Long Arm Cutting Forceps	
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	Small Dilator	
407-3306	3mm Hex Screw Driver	
412-3101	T20 Screw Wrench	

Cat.No.	Description	
407-1301	Set Screw Holder	
407-2902	Rod Template 300mm	
407-3309	4mm Hex Screw Driver	
406-1201	Rod Bender (French Bender)	
407-1403	Rod Introducer	
406-1203	Insitu Bender	
407-1001	Torque Limiting T-Handle	
20141-022	SmartLoc Block	
407-3201	Hook Driver	
407-3001	Hook Impactor	

Cat.No.	Description	
197-0703	Pedicle Hook Starter	
197-0702	Laminar Hook Starter	
407-2103	Hook Clamp	
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.
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/

Implants

Monoaxial Screw

Cat.No.	Description
131-55358	Monoaxial Screw Ø5.5mm x L35mm
131-55408	Monoaxial Screw Ø5.5mm x L40mm
131-55458	Monoaxial Screw Ø5.5mm x L45mm
131-60408	Monoaxial Screw Ø6.0mm x L40mm
131-60458	Monoaxial Screw Ø6.0mm x L45mm
131-60508	Monoaxial Screw Ø6.0mm x L50mm
131-65408	Monoaxial ScrewØ6.5mm x L40mm
131-65458	Monoaxial Screw Ø6.5mm x L45mm
131-65508	Monoaxial Screw Ø6.5mm x L50mm
131-70358	Monoaxial Screw Ø7.0mm x L35mm
131-70408	Monoaxial Screw Ø7.0mm x L40mm
131-70458	Monoaxial Screw Ø7.0mm x L45mm

Monoaxial Long-Arm Screw

Cat.No.	Description
136-60408	Monoaxial Long-Arm Screw Ø6.0mm x L40mm
136-60458	Monoaxial Long-Arm Screw Ø6.0mm x L45mm
136-60508	Monoaxial Long-Arm Screw Ø6.0mm x L50mm
136-65408	Monoaxial Long-Arm Screw Ø6.5mm x L40mm
136-65458	Monoaxial Long-Arm Screw Ø6.5mm x L45mm
136-65508	Monoaxial Long-Arm Screw Ø6.5mm x L50mm
136-70358	Monoaxial Long-Arm Screw Ø7.0mm x L35mm
136-70408	Monoaxial Long-Arm Screw Ø7.0mm x L40mm
136-70458	Monoaxial Long-Arm Screw Ø7.0mm x L45mm

Polyaxial Screw

Cat.No.	Description
134-6040R	Polyaxial Screw Ø6.0mm x L40mm
134-6045R	Polyaxial Screw Ø6.0mm x L45mm
134-6050R	Polyaxial Screw Ø6.0mm x L50mm
134-6540R	Polyaxial Screw Ø6.5mm x L40mm
134-6545R	Polyaxial Screw Ø6.5mm x L45mm
134-6550R	Polyaxial Screw Ø6.5mm x L50mm

Polyaxial Long-Arm Screw

Cat.No.	Description
139-6040F	Polyaxial Long-Arm Screw Ø6.0mm x L40mm
139-6045F	Polyaxial Long-Arm Screw Ø6.0mm x L45mm
139-6050F	Polyaxial Long-Arm Screw Ø6.0mm x L50mm
139-6540F	Polyaxial Long-Arm Screw Ø6.5mm x L40mm
139-6545F	Polyaxial Long-Arm Screw Ø6.5mm x L45mm
139-6550F	Polyaxial Long-Arm Screw Ø6.5mm x L50mm

Smooth Rod

Cat.No.	Description
132-50412	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
132-51302	Smooth Rod Ø5.5mm x L130mm
132-51502	Smooth Rod Ø5.5mm x L150mm
132-51702	Smooth Rod Ø5.5mm x L170mm
132-52002	Smooth Rod Ø5.5mm x L200mm
132-52502	Smooth Rod Ø5.5mm x L250mm

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

General Warnings, Precautions and Possible Effects

A. Postoperative Management

◆ **Wound Closure**

1. Remove all instruments and carefully check to ensure nothing is left at the surgical site of the patient.
2. The wound is subsequently closed in the routine manner.

◆ **Care for postoperation**

1. Patient may be allowed to sit in bed with back support 1-3 days after the operation.
2. Wound drains are removed 48 hours after the operation.
3 If the patient is able to be ambulated with or without crutches, he / she is allowed to do so 5 days after the operation.
4. Patients should be instructed to wear a lumbar spinal brace for 3-6 months following surgery.
5. Patient receiving implants should be instructed in full detail of the limitation of the implants, avoiding excessive loading due to inadequate activities that leads to implant failure or refracture.

B. Instructions for Patient

1. In some rare cases, progression of degenerative disease may be so advanced that the expected service life of such device may be substantially decreased. In such case, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.
2. Patients must be aware of all postoperative restrictions, particularly limitations related to occupational and sports activities.
3. Patients should be warned that non-compliance with postoperative instructions may lead to failure of the implant(s). Additional surgery may also be required to remove the device.

C. Precautions to Surgeons

1. The SmartLoc Spinal Fixation System is designed as temporary system. Bone screws are most likely to fall without proper bone grafting, or if a pseudarthosis develops.
2. The surgeons must be thoroughly knowledgeable of the mechanical and metallurgical limitations of metallic surgical implants.
3. The patient should be made aware that a metallic implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing.
4. The patient should be adequately instructed. Postoperatively care and the patient ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and that physical activity and full weight bearing have been implicated in premature failure of metallic internal fixation devices.
5. A patient who is active, debilitated or demented and can not use weight supporting device properly may be at risk particularly during postoperative rehabilitation period.

D. Precautions to Patients

1. Although the use of internal fixation implants has given the surgeons a mean of bone fixation and help generally in the management of fracture and reconstructive surgery, these implants are only intended to be a temporary device to assist normal healing are not intended to replace normal body structures. Metallic bone fixation devices are internal splints which provide a means of bone fixation while normal bone healing occurs.
2. Postoperative care is extremely important. The patient must be instructed in the limitations of this implant and must be warned regarding weight-bearing and body stress on the device prior to firm bone healing. The patient should be warned that non-compliance with postoperative instructions could lead to failure of the device and the possible need thereafter for additional surgery to remove the device.

E. Possible Adverse Effects

Patients should be advised prior to implantation surgery the possible side effects of such surgeries including:

1. Bleeding or hematoma.
2. Superficial or deep Infection. Inflammatory reaction.
3. Neurological complications, paralysis, soft tissue lesions, pain due to the surgical procedure, breakage, deformation, or migration of the implants.
4. Pedicle fracture during screw insertion.
5. Allergic reaction to the $Ti6Al_4V$ alloy.
6. Pain or/and abnormal sensation due to hardware bulkiness.
7. Delayed or non-fusion of the grafted mass. Pseudoarthrosis.
8. Bursitis.
9. Presence of metallic micro particle around the implants.
10. Bending, loosening, migration, or fracture of one or all or the implants.
11. Reduction of bone density due to the alteration of distribution of mechanical stress.
12. Loss of correction, partial or total, achieved during surgery.
13. Growth arrest or alteration of the fused vertebrae.

F. Possible Risks And Complications

1. Screw improperly positioned.
2. Incorrect fixation of implant components.
3. The shape of the implant does not match the incised wound.
4. Failure to properly fill and compress bone graft material into the bony defect.
5. A patient who is active, debilitated or demented and can not use weight supporting device properly may be at risk particularly during postoperative rehabilitation period.

G. Warnings

1. Correct selction of the implant is extremely important. The potential for satisfactory fixation and fusion are increased by the selection of the proper size, shape and design of the implant. The size and the shape of human bones present limitations on the size, shape and strength of implants.
2. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal and healthy bone. No implants can be expected to withstand indefinitely the unsupported stress of full weight bearing, proper selection can minimize the risks.
3. Implants can break when subjected to the increased loading asso ciated with delayed union or nonunion. Internal fixation appliances are load sharing devices which are used until normal healing occurs.
4. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing and activity levels will dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early fatigue (patients should be fully informed of risks of implant failure).
5. Mixing metals can cause corrosion. Dissimilar metals in contact, such as titanium screws in a stainless steel bone plate, accelerate the corrosion process of stainless steel and rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of the implant. Internal fixation devices, such as plates and screws which come in contact, must be made from like or compatible metals.
6. Surgical implants must never be reused. An explained implant should never be re-implanted.
7. The use of image intensifier with C-arm is recommended intraoperatively to assist positioning, reduction, and the elimination of complication.

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