

SmartMIS[®] Spinal Fixation System



+ Characteristics

- Double-Lead and Cortical Design
- Cortical Thread Form
- Cannulated

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Introduction

SmartMIS Spinal Fixation System is a spinal fixation system composed of cortical thread pedicle screws, smooth rods, transverse link assemblies, connectors for spinal surgery. Various sizes and styles of the implants are available for optimal adaptation of the pathology of the individual patient. Specific instruments have been designed for use with these implants.

Indications

1. Degenerative disc disease
2. Spondylolisthesis
3. Trauma (i.e., fracture or dislocation)
4. Spinal stenosis
5. Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
6. Tumor
7. Pseudoarthrosis
8. Failed previous fusion

Contraindications

1. Bone absorption, osteopenia, and/or osteoporosis
2. Any active or suspected latent infection of the spine
3. Any mental or neuromuscular disorder which might create unacceptable risk of fixation failure or complications post-operatively
4. Bone stock abnormalities, or deficiency which cannot provide adequate support and/or fixation to the implants
5. Pathological obesity
6. Open wounds
7. Metal sensitivity, documented or suspected
8. Pregnancy
9. Excessive local inflammation reaction
10. 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

All implants and instruments should be sterilized by steam autoclave following the internal hospital guidelines to achieve the degree of sterility of 10^{-6} .

The suggested parameters are as follow:

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.

CAUTION:

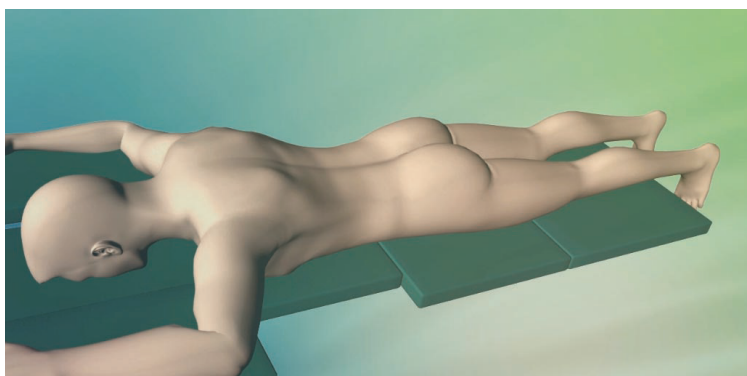
The use of sodium hydroxide (NaOH) is prohibited.

Avoid the use of corrosive products and instruments including abrasive sponges and metal brushes.

Surgical Technique

○ Patient Position

Patient is positioned in prone position with abdomen free from pressure. This position aids in the maintenance of normal lumbar lordosis and the reduction of abdominal compression, minimizing epidural venous bleeding. C-arm Fluoroscopic image intensifier is used to supervise throughout the surgery.

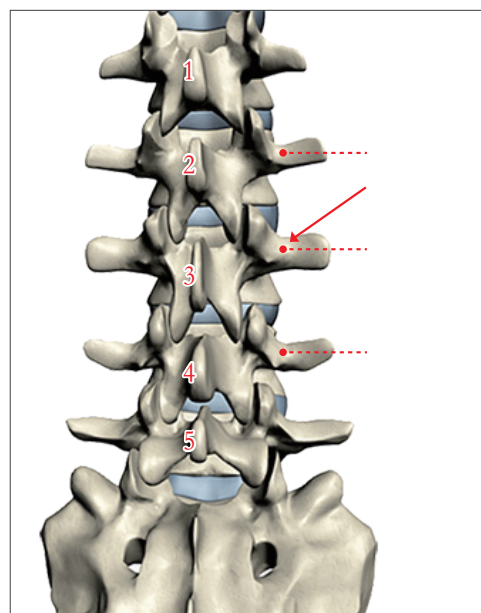


○ Locate the Pedicle Entry Points

The use of the SmartMIS Spinal Fixation 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 instrumented and unfused segments.



The use of the SmartMIS Spinal Fixation System in 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



Figure 1

01 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.

Determine the angle of entry and penetrate the probing cortex with the **Awl (With Stop)** (406-0201) to mark that position.

(Figure 1)

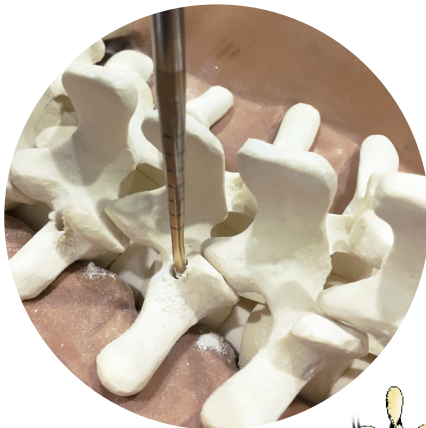


Figure 2

Using the **Probe** (406-0301 or 406-0302) gently deepen the hole through the pedicle cancellous bone to the desired depth.

(Figure 2)

The probe is placed through the pedicle into the body of the vertebrae with C-Arm Fluoroscopy assistor approximately.

In some cases such as with osteoporotic bone, the probe may not be used but the **4mm Guide Pin** (406-3104, 406-3114) can be placed directly into the pedicle to vertebral body for checking the enter point of screw trajectory.



406-0201

Awl (With Stop)



406-0301

Probe



406-0302

Straight Probe



406-3104

4mm Guide Pin



406-3114

4mm Guide Pin



Figure 3

Select the handle to attach the instruments is a normal grip design. For operation smoothly, the **T-handle (406-0101)** has no ratchet.

But the **Ball Handle (407-0104)** is a ratchet function and with cannula hole design. (Figure 3)



Figure 4

Use the **Tap (433-0504~433-0507)** to prepare the screw thread if need be.

The **Sensor (406-0401)** depth sounding is used to confirm the continuity of the cortical wall of the pedicle should medial or inferior perforation occurs, establishing another orientation and position of the pedicle passage is indicated. (Figure 4)



406-0101

T-Handle



407-0104

Ball Handle, Ratchet



433-0524~433-0527

4~7mm Tap



406-0401

Sensor

02 Screw Insertion

Select the appropriate screw driver by screw shape; please refer to the index in the table.

Fully insert the end of the Screw Driver into the appropriate length screw head, thread the sleeve into the screw head to provide a stable insertion, and then push the cover directly on the sleeve to prevent loosening during rotation. If want to release sleeve, pull the cover back and anticlockwise the sleeve. (Figure 5 and 6)

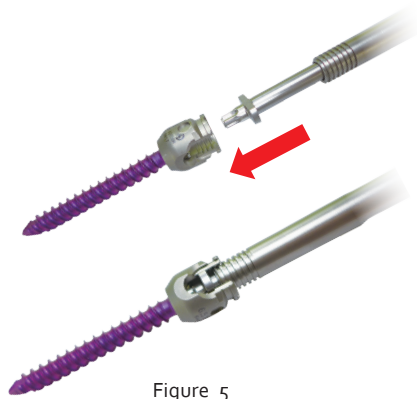


Figure 5

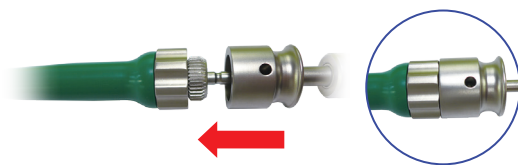


Figure 6

CAUTION:

If the tip of Multi-axial Screw Driver/Multi-axial Long-Arm Screw Driver is not fully inserted into the Multiaxial Screw, the screw will not remain stable and effect screw insertion.

Insert the pedicle screw along pre-prepared screw hole. Once the screw is inserted, the sleeve is unscrewed and the Screw Driver disengaged from the screw.





Figure 7



Figure 8

03 Rod Preparation and Insertion

The spinal curve should be a gentle lordotic curve; use the **Rod Template (407-2901)** to be the line drawn on top of the screw heads for checking lordotic curve.

The rod curve is adjusted according to the Rod Template by the **Rod Bender (406-1201)**.

(Figure 7)

Use the **Rod Holder (406-1301)** to place rod into the bottom of screw heads from either the cephalad or caudad direction.

04 Star Set Screw Insertion

The Star Set Screws are inserted into the implants using the **Star Set Screw Holder (433-1301)**, and tighten the Star Set Screws using the T25 Set Screw Driver.

(Figure 8)

CAUTION:

The T25 Set Screw Holder should not be used to tighten the Star Set Screws, otherwise instrument will be damaged.



407-2901

Rod Template
150mm



406-1201

Rod Bender



406-1301

Rod Holder



433-1301

Star Set Screw Holder



Figure 7



Figure 10

05 Rod Reduction

If the rod is not fully fixed to the bottom of the screw head, the **Rod Pusher (406-2601)** can help to press the rod or use the **Rod Reducer (433-1401)** to fully press the rod to the bottom of the screw head, and insert a T25 Set Screw Driver with Star Set Screw which through the hole of Rod Reducer to tighten it. (Fig. 7).

CAUTION:

The Rod Reducer may be used on standard screws, but not long-arm screws.

06 Rod Adjustment

If the rod needs be rotated, use the **Star Set Screw-driver (433-3305)** attached **with T-Handle (406-0101)** or **Ball Handle, Ratchet (407-0104)** to release a set screw at the end of the rod and use a **5mm Rotator Bar (406-3005)** to stick the end of the rod, then rotate the rod until it reaches the proper direction. (Figure 10)

Usually deformity/scoliosis correction use long segment rods, the **Rod Clamp (407-2101)** and the **Insitu Bender (406-1203)** can be used to adjust the curve of long Segment.



406-2601

Rod Pusher



406-3005

5mm Rotator Bar



407-2101

Rod Clamp



406-1203

Insitu Bender



Figure 11



Figure 12

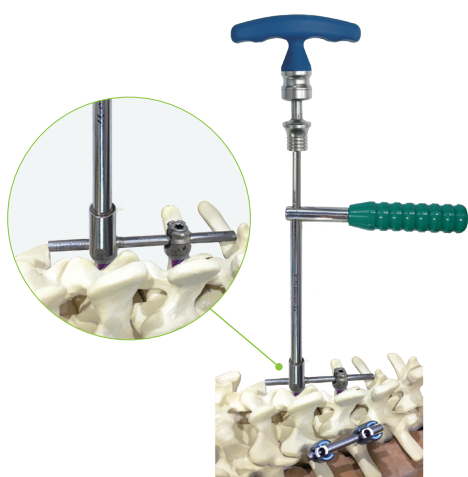


Figure 13

07 Distraction and Compression

If either compression or distraction is needed, one side of the motion segment should be tightened and another be provisionally loosened.

The **Angled Compressor (407-0901)** or the **Angled Distractor (407-0902)** is placed on the rod that can be used to adjust the distance between the screws.

Once it has been achieved, tightening screw again.

(Figure 11 and 12)

08 Final Tightening

After all the implants are firmly seated, the set screws suppress the movement between the rod and the screw cup. But it still need final tightening set screw in order to avoid rod loosening.

The **Anti-Torque Wrench, Notch Ø5.5mm (433-3402)** should be held screw head and rod firmly to prevent torqueing of the construct while final tightening. Assemble the **Torque Limiting T-Handle (451-1001)** to the **Star Set Screwdriver (433-3305)**, and insert to set screw through the Anti-torque Wrench. Rotate the Torque Limiting T-Handle until it clicks, which means it achieve the final tightening torque of 10Nm and avoid over screwing and destroy implants.

(Figure 13)



407-0901

Angled Compressor



407-0902

Angled Distractor



433-3402

Anti-Torque Wrench,
Notch Ø5.5mm



451-1001

Torque Limiting
T-Handle



433-3305

Star Set Screwdriver

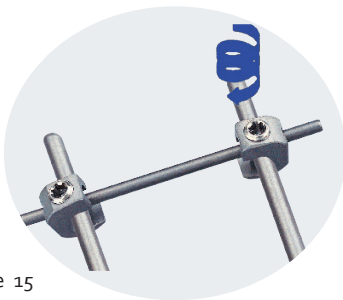
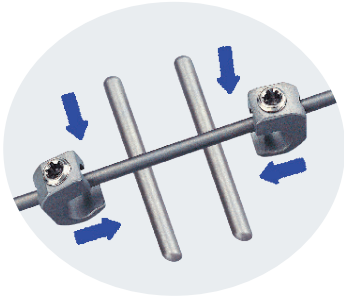


Figure 15

09 Transverse Link Placement

If multi-segment fixation, the Transverse Link can be assembled to assist construct stability to withstand rotation and lateral bending of the vertebral column.

The Rod Holder holds the Transverse Link to cross on two rods, and the hooks of Transverse Link capture and position the rods. After that, the screws are tightened by the **T2o Screw Wrench (412-3101)**.

(Figure 14 and 15)

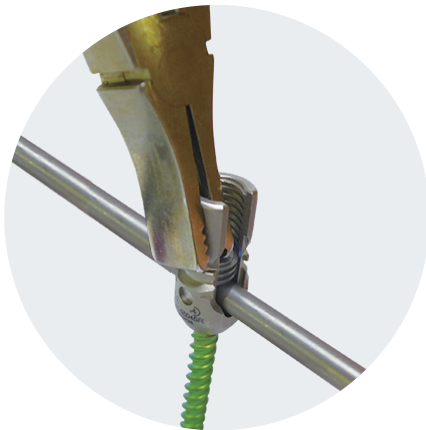


Figure 16

10 Cutting off

When insert the long-arm screw done the final tightening, use the **Long Arm Cutting Forceps (407-2102)** to remove the remaining tab of the long arm screw.

(Figure 16)



412-3101

T2o Screw Wrench



407-2102

Long Arm
Cutting Forceps

Instrument Set



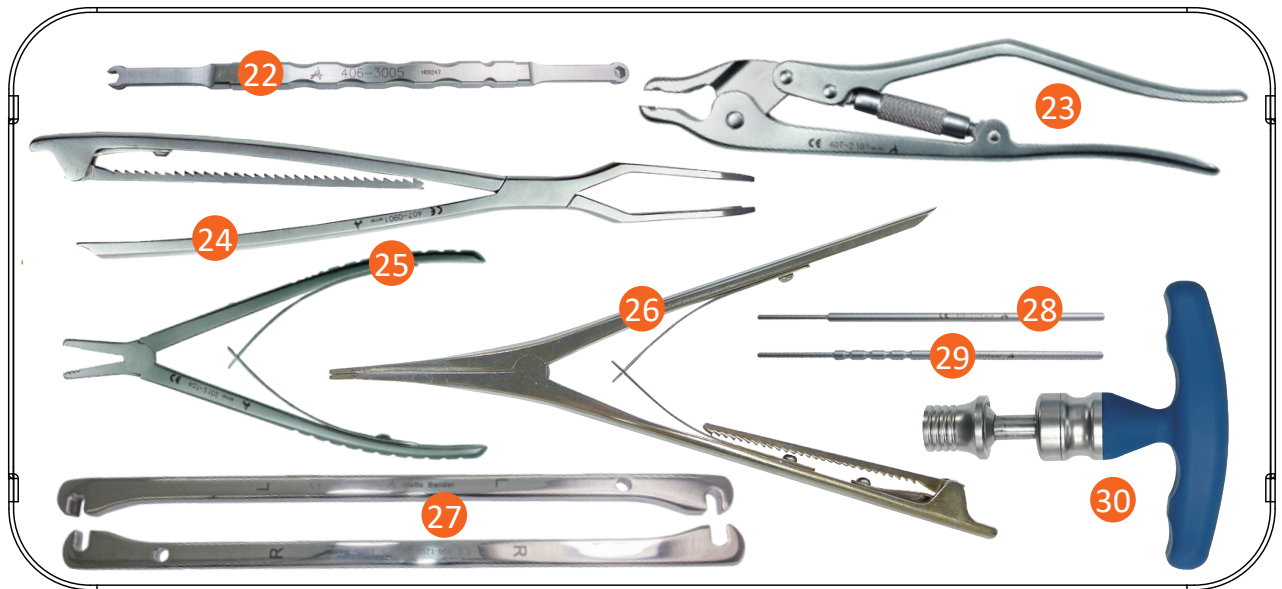
Instrument Tray 1

Cat.No.	Description	Q'nty
① 433-0524~433-0527	4~7mm Tap (4 size each 1)	4
② 433-3301	Multiaxial Screwdriver	2
③ 433-3302	Multiaxial Long-Arm Screwdriver	2
④ 406-0201	Awl (With Stop)	1
⑤ 406-0301	Probe	1
⑥ 406-0302	Straight Probe	1
⑦ 407-0104	Ball Handle, Ratchet	1



Instrument Tray 2

Cat.No.	Description	Q'nty
11 433-3305	Star Set Screwdriver	2
12 433-3402	Anti-Torque Wrench, Notch Ø5.5mm	1
13 433-1301	Star Set Screw Holder	2
14 407-2901	Rod Template 150mm	1
15 406-1201	Rod Bender	1
16 406-0401	Sensor	1
17 412-3101	T20 Screw Wrench	1
18 406-2601	Rod Pusher	1
19 433-1401	Rod Reducer	1
20 406-0101	T-Handle	1
21 406-1301	Rod Holder	1



Instrument Tray 3

Cat.No.	Description	Q'nty
22 406-3005	5mm Rotator Bar	2
23 407-2101	Rod Clamp	1
24 407-0901	Angled Compressor	1
25 407-2102	Long Arm Cutting Forceps	1
26 407-0902	Angled Distractor	1
27 406-1203	Insitu Bender	1
28 406-3104	4mm Guide Pin	4
29 406-3114	4mm Guide Pin	4
30 451-1001	Torque Limiting T-Handle	1

Instruments

Cat.No.	Description	
406-0101	T-Handle	
406-0201	Awl (With Stop)	
406-0301	Probe	
406-0302	Straight 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	
406-3104	4mm Guide Pin	

Cat.No.	Description	
407-0104	Ball Handle, Ratchet	
407-0901	Angled Compressor	
407-0902	Angled Distractor	
451-1001	Torque Limiting T-Handle	
407-2101	Rod Clamp	
407-2102	Long Arm Cutting Forceps	
407-2901	Rod Template 150mm	
412-3101	T20 Screw Wrench	
433-0101	T-Handle, Ratchet*	
433-0524 433-0525 433-0526 433-0527	4mm Tap 5mm Tap 6mm Tap 7mm Tap	
433-1301	Star Set Screw Holder	

* Optional

Cat.No.	Description	
433-1401	Rod Reducer	
433-3301	Multiaxial Screwdriver	
433-3302	Multiaxial Long-Arm Screwdriver	
433-3305	Star Set Screwdriver	
433-3402	Anti-Torque Wrench, Notch Ø5.5mm	
20141-022	SmartLoc Block	
99902-042	SmartMIS Product Case, Metal Lid	
99900-042	SmartMIS Instrument Case, Metal Lid	

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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