

SmartMIS[®] Spinal Fixation System



+ Characteristics

- Cortical Thread form small pitch provides enhanced fixation
- Complement for minimally invasive, percutaneous

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Introduction

The SmartMIS Spinal Fixation System is a state of art pedicle screw with cortical thread and double thread for minimally invasive surgery. The instrumentation is ergonomically designed to allow for either a true percutaneous or Wiltse approach, and it offers a simple, precise and efficient solution to spinal fixation.

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 postoperatively
- 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

This is intended as a guide only. There are multiple techniques for the insertion of pedicle screws and, as with any surgical procedure, a surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use insert for complete system description, indications and warning.

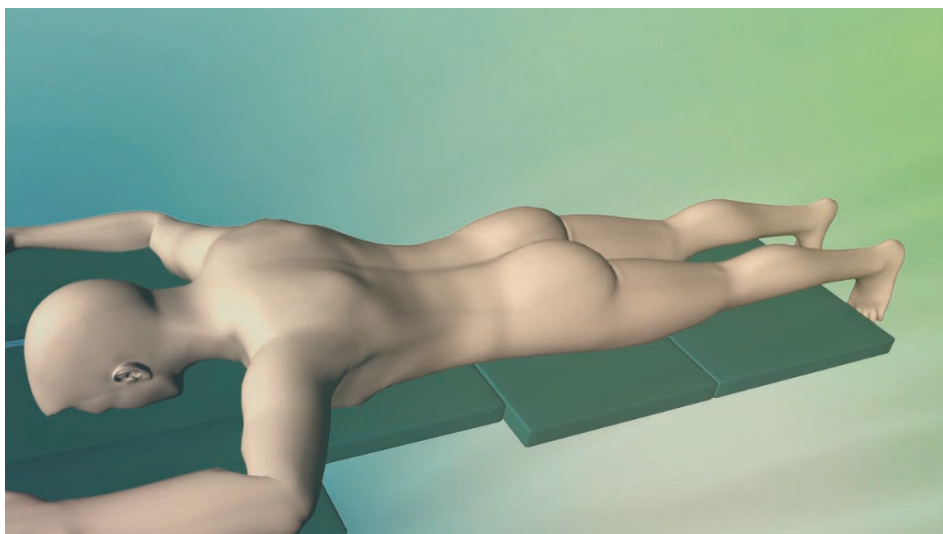
Surgical Technique

○ Preoperative preparation

Preoperative preparation can be useful in determining the proper targeting and screw trajectory. AP / Lateral views demonstrate approximate screw positioning at multiple levels of the thoracolumbar spine. Graft placement depends upon the medical judgment of the surgeon.

○ Patient Position

The patient should be positioned prone lying face down on a radiolucent table. Confirm the C-Arm will allow for easy rotation in the lateral, oblique, and A/P positions around the table (Fig. 1).



patient position of the posterior lumbar operation

Figure 1

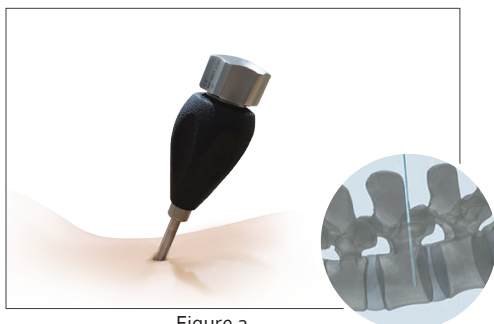


Figure 2

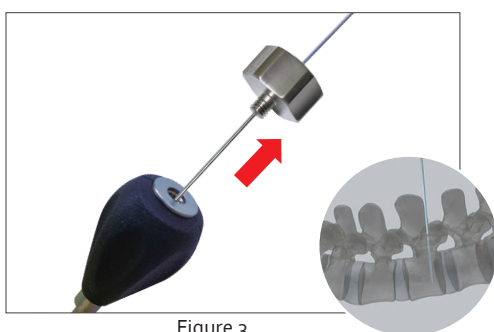


Figure 3

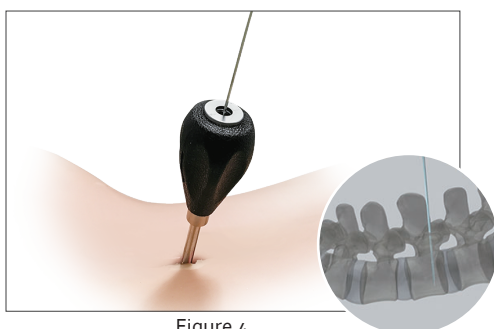


Figure 4

01 Guide Wire Placement

Make an incision through the skin and fascia. The typical starting point is 3-4 cm off the midline. Make a skin incision 2 cm over each pedicle for screw insertion, and add 0.5 cm for rod insertion site.

Insert the **Threaded Awl (433-0201)** (Fig. 2) down to the surface of the pedicle and dock the tip on the bony anatomy of the desired level and confirm placement with A/P fluoroscopy.

Adjustments to the entry angle and the trajectory should be made until the proper position is attained, and rotate clockwise to perforate the cortex of the pedicle and down through the pedicle.

Once proper placement is confirmed, remove the **Threaded Awl Needle (407-0311)** (Fig. 3)

Insert the **Guide Wire, Ø1.5×450mm (407-1105)** through the cannula, and advance it just past the tip of the targeting. By using fluoroscopy to ensure the location of the Guide Wire, after that, remove the Threaded Awl, and leave the Guide Wire in place. (Fig. 4)

NOTE:

Use fluoroscopy to monitor the position of the Threaded Awl and Guide Wire during insertion.



433-0201

Threaded Awl



407-0311

Threaded Awl Needle



407-1105

Guide Wire, Ø1.5×450mm

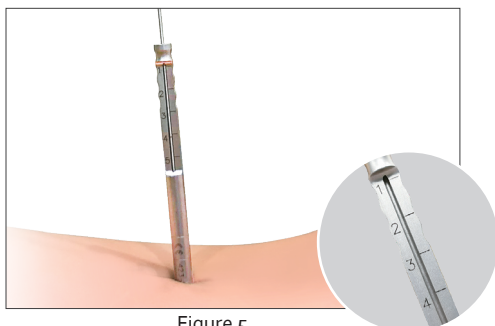


Figure 5

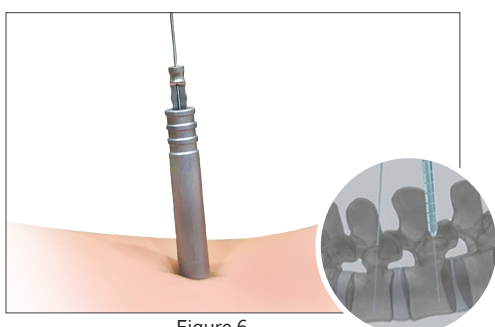


Figure 6

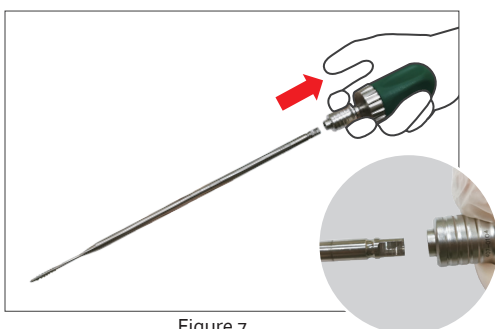


Figure 7

02 Tissue Dilation & Tapping

Insert the **Small Dilator (423-7201)** over the Guide Wire until the tip reaches the pedicle entry point. Using the laser marking on the Guide Wire, the depth of the guidewire. (Fig. 5)

Use the dilator sequentially to dilate soft tissue of the path to the pedicle. Insert the **Middle Dilator (433-7202)** through the Small Dilator, and then remove the Small Dilator. (Fig. 6)

Select the appropriate tap size and connect it with the **Ball Handle, Ratchet (407-0104)** or **T-Handle, Ratchet (433-0101)**. (Fig. 7)

NOTE:

When using the quick connector of the handle, push the O-ring down before inserting the combination instrument. After inserting the instrument into the bottom, loosen the O-ring to lock it. Finally, gently pull the instrument to confirm that the combination is complete.



423-7201

Small Dilator



433-7202

Middle Dilator



407-0104

Ball Handle, Ratchet



433-0101

T-Handle, Ratchet

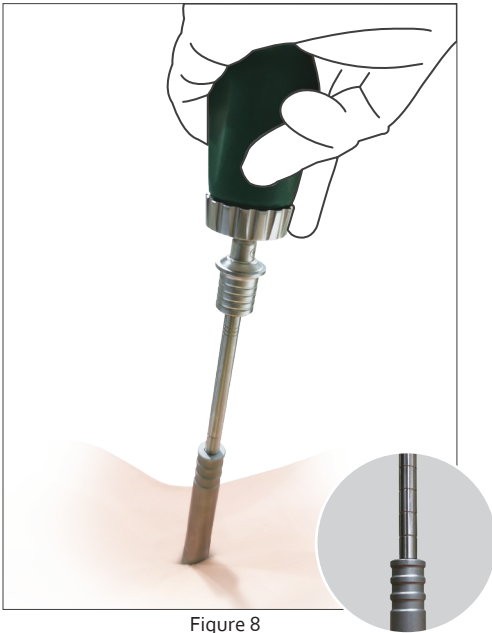


Figure 8

In support of the pedicle screw preparation, it is recommended to tap after introducing **Middle Dilator (433-7202)**. (Fig. 8)

NOTE:

The Guide Wire must be held in position so that it is not pushed forward.

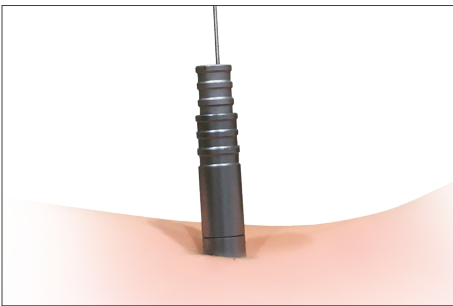


Figure 9

After tapping, continue to dilate tissue by **Large Dilator (433-7203)** (Fig. 9), and remove the Middle Dilator. (Fig. 10)

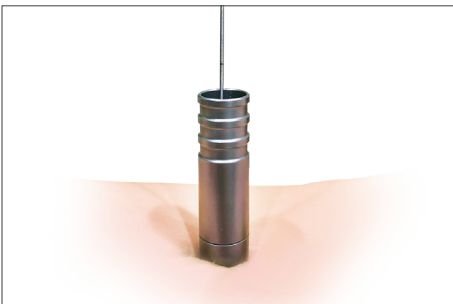


Figure 10



433-7203

Large Dilator



433-0524~433-0527

Cannulated Cortex Tap
(4mm ~ 7mm)

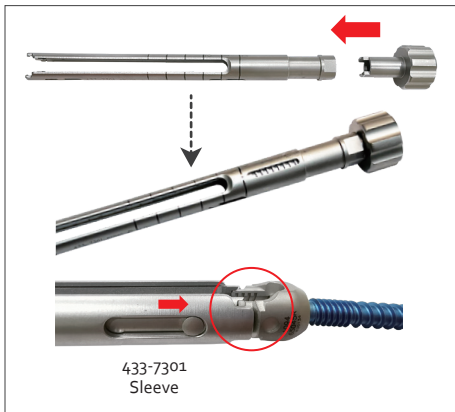


Figure 11

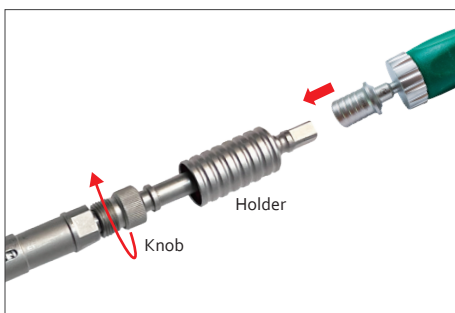


Figure 12



Figure 13

03 Sleeve Attachment

Insert the **Sleeve Driver (433-3308)** into top of the **Sleeve (433-7301)** to control inner part for loosen or tighten. Insert the polyaxial screw head into the distal end of the sleeve and rotate 90°, rotate the Sleeve Driver clockwise until it stops. The screw is properly positioned until the knob matches the bottom of the observation window. (Fig. 11)

04 Screw Insertion

T25 Cannulated Screwdriver (433-3307) is inserted into polyaxial screw through the Sleeve. The Screwdriver is securely fixed in the screw head of the screw to be implanted by tightening the knob on the Screwdriver to the proximal threads on the Sleeve. The polyaxial movement of the screw thread is now blocked and axially aligned to the Screwdriver.

Then, assemble the holder with the Screwdriver. (Fig. 12)

Attach the Handle and insert the screw via the **Guide Wire (407-1105)**, then rotate the handle clockwise to advance the screw. (Fig. 12 and 13)

The markings on the Sleeve can indicate the relative implantation depth of the screw during insertion. (Fig. 13)

NOTE:

Monitor the screw position by using fluoroscopy and then remove the Large Dilator.



433-3308

Sleeve Driver



433-7301

Sleeve



433-3307

T25 Cannulated Screwdriver



433-0101

T-Handle, Ratchet



407-0104

Ball Handle, Ratchet



Figure 13

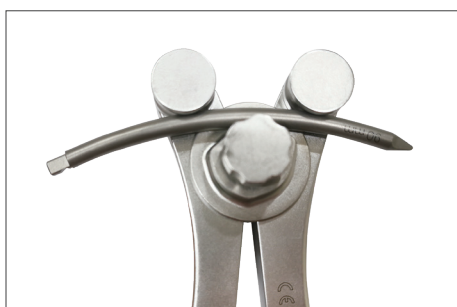


Figure 14

05 Rod Measurement

Based on the screw positions, insert the **Rod Measure (423-4802)** down to the bottom of the Sleeve and determine the length of Percutaneous Rod. (Fig. 13)

06 Rod Preparation and Insertion

As needed, the rod can be brought into the suitable shape by using **Rod Bender (406-1201)**. Do not apply reverse bending to a pre-bend rod, as this may weaken the final construct. (Fig. 14)

NOTE:

The curve must be on the same plane for the rod to insert between the Sleeves.



423-4802

Rod Measure



406-1201

Rod Bender
(french bender)

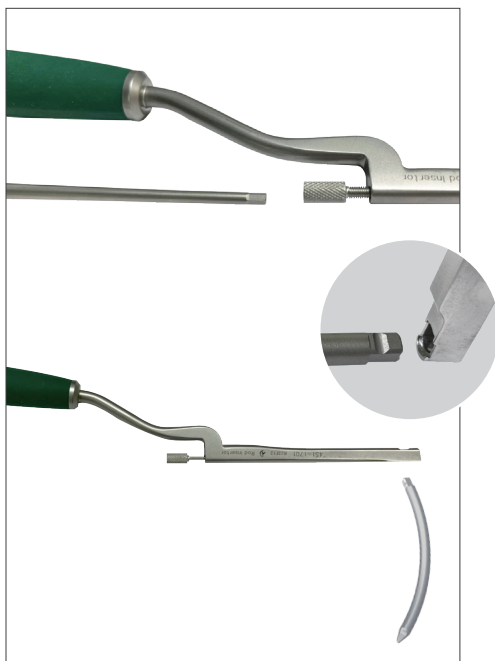


Figure 15

Assemble the square end of the rod into the **Rod Insertor (451-1701)**, and use **Rod Insertor Screwdriver (451-3303)** to turn the screw clockwise to secure the rod firmly. (Fig. 15)

Insert the rod into the Sleeve as far as possible along the outside of the Sleeve, and advance it down until it touches the screw cup or reaches the maximum depth allowed by the space.

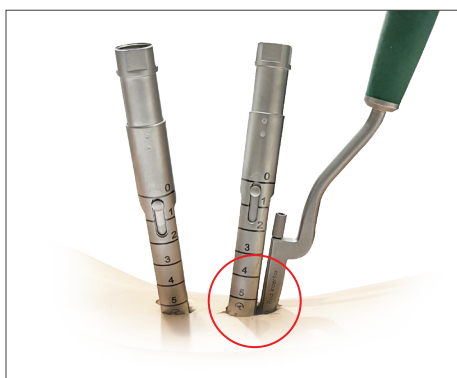
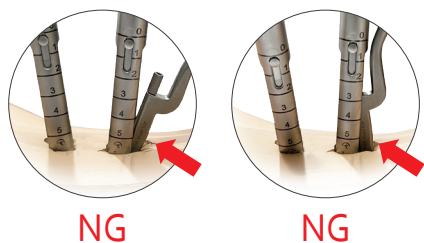


Figure 16

The Sleeves must be aligned in parallel when delivering the rod. Place the rod completely into screw cups in the same row, and use fluoroscopy to confirm the position. (Fig. 16)



NG

NG



451-1701

Rod Insertor



451-3303

Rod Insertor Screwdriver

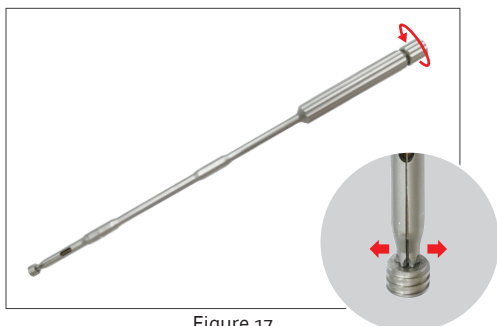


Figure 17



Figure 18



Figure 19

07 Star Set Screw Insertion

The shaft of the **Star Set Screw Holder (433-1304)** can control the size of the tip. Rotate the shaft counterclockwise to reduce the volume of the tip, which is convenient for inserting the star set screw, and then rotate clockwise to enlarge the tip volume to hold the star set screw. (Fig. 17)

NOTE:

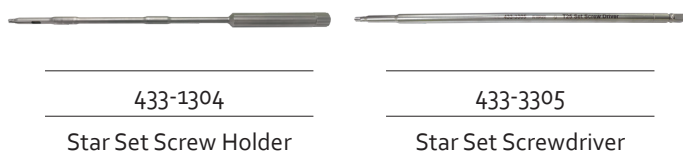
If the Star Set Screw Holder is not loosened and the star set screw is pulled out, the implant and the instrument will be damaged.

Insert the star set screws by using **Star Set Screw holder (4433-1304)**(Fig. 18) and fixed firmly with **Star Set Screwdriver(433-3305)**.

Before removing the **Rod Insertor (451-1701)**, please make sure the rod is completely fixed and repeat the step above.(Fig.19)

NOTE:

If the rod is not fixed firmly, the direction of rod curve will rotate when the Rod Insertor is released.



433-1304

Star Set Screw Holder

433-3305

Star Set Screwdriver



Figure 20

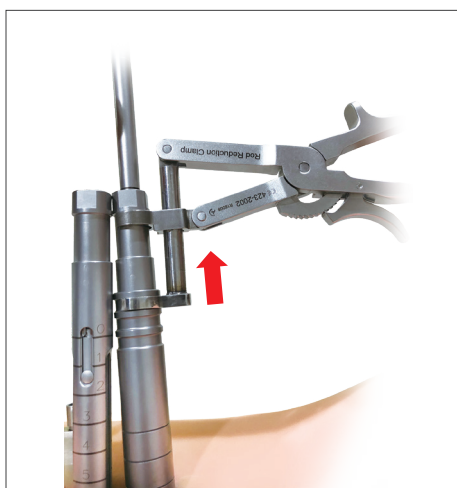


Figure 21

08 Rod Reduction

When the star set screw cannot touch the thread in the screw cup, the rod needs to be pressed down by assistance instruments.

Put the Large Dilator over the Sleeve, and insert **Rod Persuader (433-1402)** into the grooves respectively (Fig. 20). Hold the handle of Rod Persuader so that the rod is pressed into the screw cup and insert the star set screw simultaneously. (Fig. 21)



433-1402

Rod Persuader

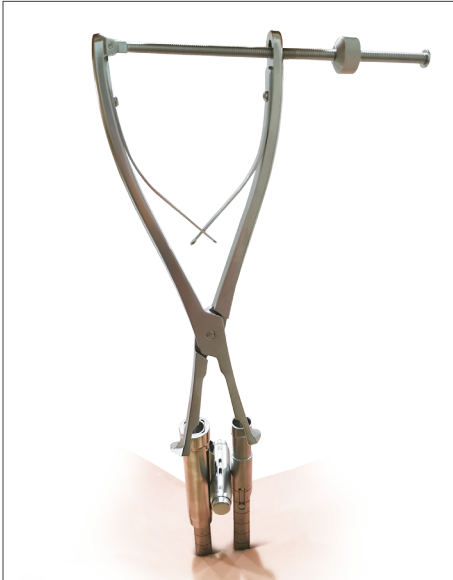
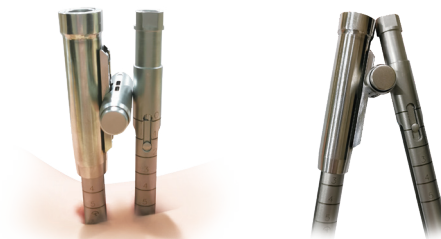


Figure 22

09 Compression and Distraction

The **Adjustable Fulcrum (433-0901)** is loaded to the top of the Sleeve and moves the bar as the leverage point by depressing both buttons on the Adjustable Fulcrum.

Loosen the star set screw with the longer side of rod, use the **Rod Compressor (423-0903)** to adjust the distance between Sleeves, and then fix it by tightening star set screw. (Fig. 22)



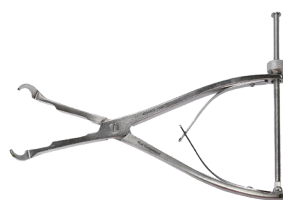
NOTE:

Avoid pulling the rod out of the screw head and check the final position by fluoroscopy.



433-0901

Adjustable Fulcrum



423-0903

Rod Compressor



Figure 23

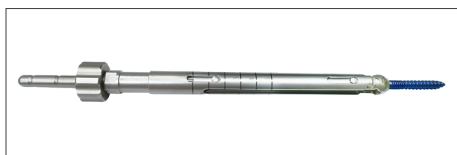


Figure 24



Figure 25

10 Screw Cup Retrieve

Use the **Screw Cup Retriever (433-1303)** to reattach if the tulip cup and the Sleeve are loosened and then tighten the Sleeve again by **Sleeve Driver (433-3308)**. (Fig. 24)

11 Final Tightening

Tightening the star set screw by using **Torque Limiting T-Handle (451-1001)** which is 10Nm and **Star Set Screwdriver (433-3305)** to avoid damaging the implant.

To secure final tightening, place the **Counter Torque Wrench (433-3401)** along the Sleeve and ensure the notches of the Counter Torque is seated in the Rod.

Introducing the Star Set Screwdriver into star set screw, and then turn it clockwise until with an audible click. (Fig. 25)



433-1303

Screw Cup Retriever



451-1001

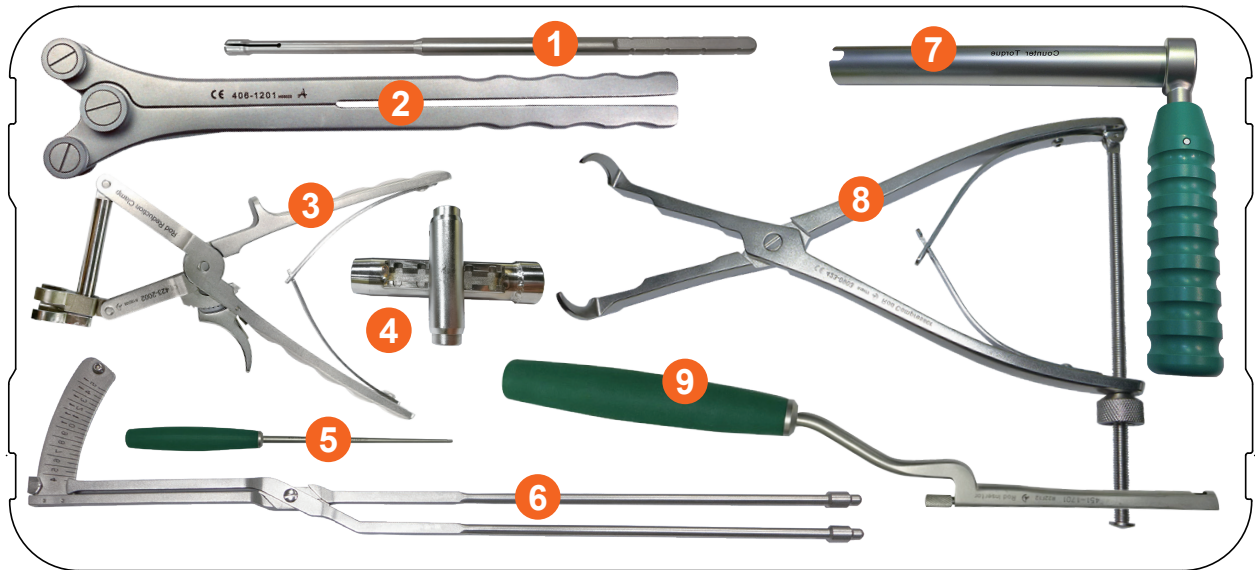
Torque Limiting T-Handle



433-3401

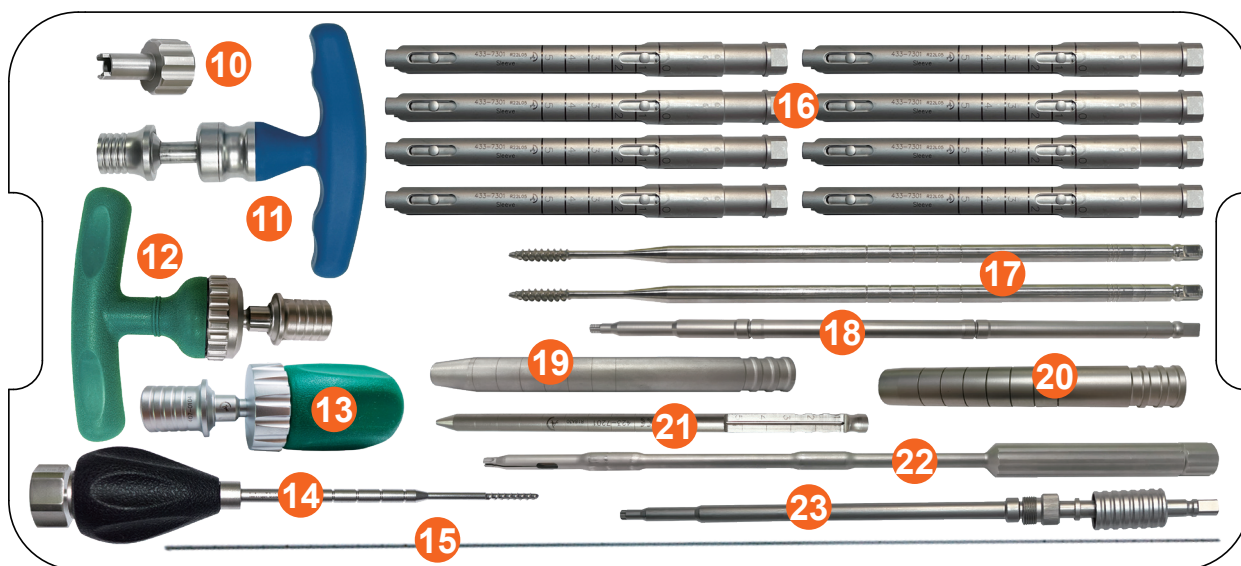
Counter Torque Wrench

Instrument Set



Instrument Tray 1

Cat.No.	Description	Q'nty
① 433-1303	Screw Cup Retriever	1
② 406-1201	Rod Bender (french bender)	1
③ 433-1402	Rod Persuader	1
④ 433-0901	Adjustable Fulcrum	1
⑤ 451-3303	Rod Insertor Screwdriver	1
⑥ 423-4802	Rod Measure	1
⑦ 433-3401	Counter Torque Wrench	1
⑧ 423-0903	Rod Compressor	1
⑨ 451-1701	Rod Insertor	1



Instrument Tray 2

Cat.No.	Description	Q'nty
10 433-3308	Sleeve Driver	1
11 451-1001	Torque Limiting T-Handle	1
12 433-0101	T-Handle, Ratchet	1
13 407-0104	Ball Handle, Ratchet	1
14 433-0201	Threaded Awl	1
407-0311	Threaded Awl Needle	1
15 407-1105	Guide Wire, Ø1.5×450mm	8
407-1106	Guide Wire, Ø1.5×500mm	*
16 433-7301	Sleeve	8

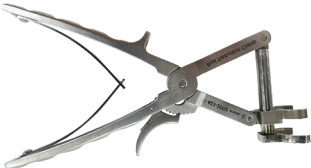
* Optional

Cat.No.	Description	Q'nty
17 433-0524	4mm Cannulated Cortex Tap	1
433-0525	5mm Cannulated Cortex Tap	1
433-0526	6mm Cannulated Cortex Tap	1
433-0527	7mm Cannulated Cortex Tap	1
18 433-3305	Star Set Screwdriver	2
19 433-7202	Middle Dilator	1
20 433-7203	Large Dilator	1
21 423-7201	Small Dilator	1
22 433-1304	Star Set Screw Holder	2
23 433-3307	T25 Cannulated Screwdriver	2

Instruments

Cat.No.	Description	
406-0101	T-Handle*	
406-1201	Rod Bender (french bender)	
407-0104	Ball Handle, Ratchet	
407-0311	Threaded Awl Needle	
407-1105 407-1106	Guide Wire, Ø1.5×450mm Guide Wire, Ø1.5×500mm*	
423-0903	Rod Compressor	
423-4802	Rod Measure	
423-7201	Small Dilator	
433-0101	T-Handle, Ratchet	
433-0201	Threaded Awl	

* Optional

Cat.No.	Description	
433-0524 433-0525 433-0526 433-0527	4mm Cannulated Cortex Tap 5mm Cannulated Cortex Tap 6mm Cannulated Cortex Tap 7mm Cannulated Cortex Tap	
433-0901	Adjustable Fulcrum	
433-1303	Screw Cup Retriever	
433-1304	Star Set Screw Holder	
433-1402	Rod Persuader	
433-3305	Star Set Screwdriver	
433-3307	T25 Cannulated Screwdriver	
433-3308	Sleeve Driver	
433-3401	Counter Torque Wrench	
433-7202	Large Dilator	

Cat.No.	Description	
433-7203	Large Dilator	
433-7301	Sleeve	
451-1001	Torque Limiting T-Handle	
451-1701	Rod Insertor	
451-3303	Rod Insertor Screwdriver	
99901-042	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 time for 30 minutes.

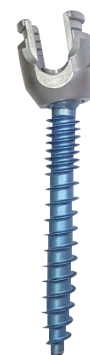
Steam Wrapped Dynamic-Air-Removal (Pre-vacuum) Cycle at 132 °C/ 270 °F for 4 minutes, dry time for 30 minutes.

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/>

Implants

Multiaxial Percutaneous Cortex Screw

Cat.No.	Description
1094-45030R	Multiaxial Percutaneous Cortex Screw Ø 4.5 x L 30mm
1094-45035R	Multiaxial Percutaneous Cortex Screw Ø 4.5 x L 35mm
1094-45040R	Multiaxial Percutaneous Cortex Screw Ø 4.5 x L 40mm
1094-50030R	Multiaxial Percutaneous Cortex Screw Ø 5.0 x L 30mm
1094-50035R	Multiaxial Percutaneous Cortex Screw Ø 5.0 x L 35mm
1094-50040R	Multiaxial Percutaneous Cortex Screw Ø 5.0 x L 40mm
1094-50045R	Multiaxial Percutaneous Cortex Screw Ø 5.0 x L 45mm
1094-55035R	Multiaxial Percutaneous Cortex Screw Ø 5.5 x L 35mm
1094-55040R	Multiaxial Percutaneous Cortex Screw Ø 5.5 x L 40mm
1094-55045R	Multiaxial Percutaneous Cortex Screw Ø 5.5 x L 45mm
1094-60040R	Multiaxial Percutaneous Cortex Screw Ø 6.0 x L 40mm
1094-60045R	Multiaxial Percutaneous Cortex Screw Ø 6.0 x L 45mm
1094-60050R	Multiaxial Percutaneous Cortex Screw Ø 6.0 x L 50mm
1094-60055R	Multiaxial Percutaneous Cortex Screw Ø 6.0 x L 55mm
1094-65040R	Multiaxial Percutaneous Cortex Screw Ø 6.5 x L 40mm
1094-65045R	Multiaxial Percutaneous Cortex Screw Ø 6.5 x L 45mm
1094-65050R	Multiaxial Percutaneous Cortex Screw Ø 6.5 x L 50mm
1094-65055R	Multiaxial Percutaneous Cortex Screw Ø 6.5 x L 55mm
1094-70040R	Multiaxial Percutaneous Cortex Screw Ø 7.0 x L 40mm
1094-70045R	Multiaxial Percutaneous Cortex Screw Ø 7.0 x L 45mm
1094-70050R	Multiaxial Percutaneous Cortex Screw Ø 7.0 x L 50mm



Pre-Bend Rod

Cat.No.	Description
1034-10408	Pre-Bend Rod Ø 5.5 x L 40mm
1034-10458	Pre-Bend Rod Ø 5.5 x L 45mm
1034-10508	Pre-Bend Rod Ø 5.5 x L 50mm
1034-10558	Pre-Bend Rod Ø 5.5 x L 55mm
1034-10608	Pre-Bend Rod Ø 5.5 x L 60mm
1034-10658	Pre-Bend Rod Ø 5.5 x L 65mm
1034-10708	Pre-Bend Rod Ø 5.5 x L 70mm
1034-10758	Pre-Bend Rod Ø 5.5 x L 75mm
1034-10808	Pre-Bend Rod Ø 5.5 x L 80mm
1034-10858	Pre-Bend Rod Ø 5.5 x L 85mm
1034-10908	Pre-Bend Rod Ø 5.5 x L 90mm
1034-10958	Pre-Bend Rod Ø 5.5 x L 95mm
1034-11008	Pre-Bend Rod Ø 5.5 x L 100mm



Star Set Screw

Cat.No.	Description
1075-08028	Star Set Screw Ø 8.5 x L 5mm



NOTE

NOTE



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