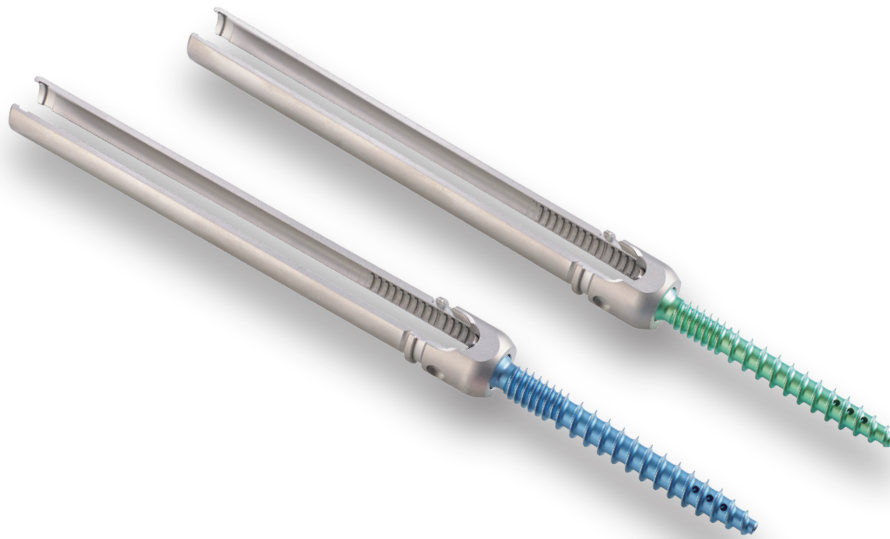


ASATM

Spinal Fixation System



+ Characteristics

- Low Profile Design
- Cortical Threaded
- Cannulated and Perforated

Contents



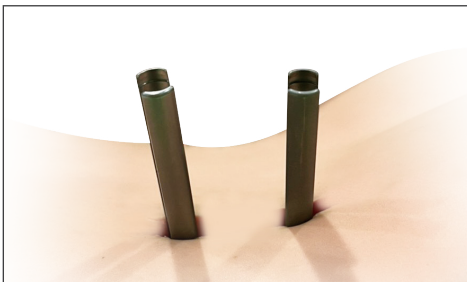
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Introduction

The evolution of spinal surgery has been gradually changing from traditional open wound surgery to minimally invasive spine (MIS) surgery. MIS has been popular in recent years due to reduced intraoperative complications, muscle damage and lower blood loss around the surgical site.

A-SPINE introduced a pedicle screw fixation system for minimally invasive percutaneous surgery of the posterior spine, which reduced the need to attach sleeves on screws, increased the convenience of the surgical procedure, reduced the number of instruments required and the time required to place pedicle screws using minimally invasive techniques.

Features and Benefits

Multiaxial Perforated Cortex Screw

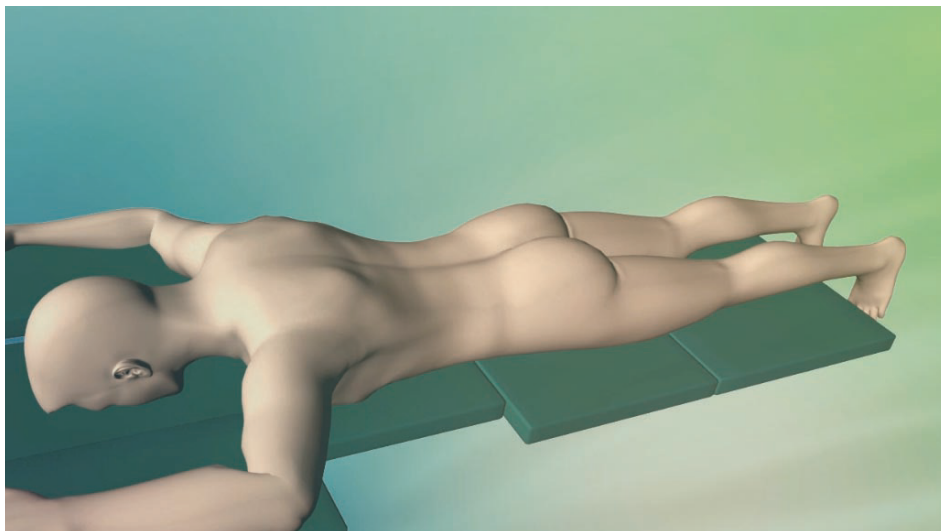
- Cannulated Screw: 1.5mm
- Cannulated Poly Axial Screw: 360° total angulation.
- Long Arm Tab Design:
Reduces damage to muscles and soft tissues
- Perforated:
Option of cement delivery for augmented screw fixation
- Cortical Threaded:
Provides enhanced fixation
- Reduction



Surgical Technique

○ Positioning

- The patient should be positioned in prone.
- Use a radiolucent operating table which does not affect C-arm operation to avoid affecting intraoperative image interpretation.



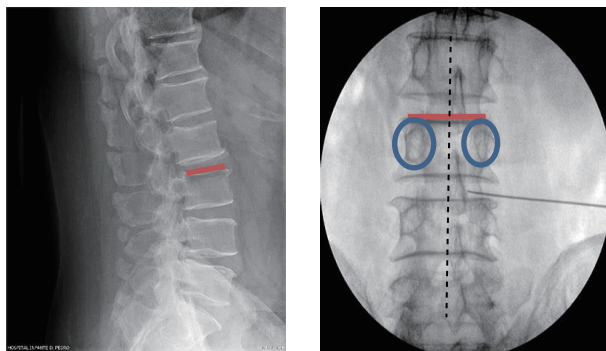
○ Preoperative planning

- By adjusting the C-arm cantilever, ensure that the surgical site and the pedicle can be clearly presented. Record the angle and position of the cantilever at the same time.
- Use AP view to locate the center point and the two sides of the pedicle, and please make a mark on the patient's back skin.
- According to the different conditions of each vertebral body, it may be necessary to relocate with C-arm to ensure the implantation process is safe and accurate.

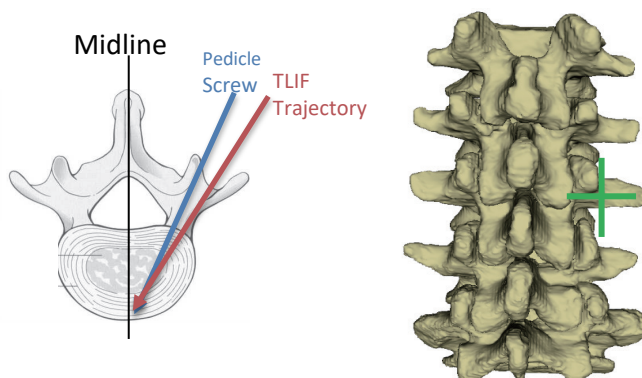


○ Pedicle identification and incision planning

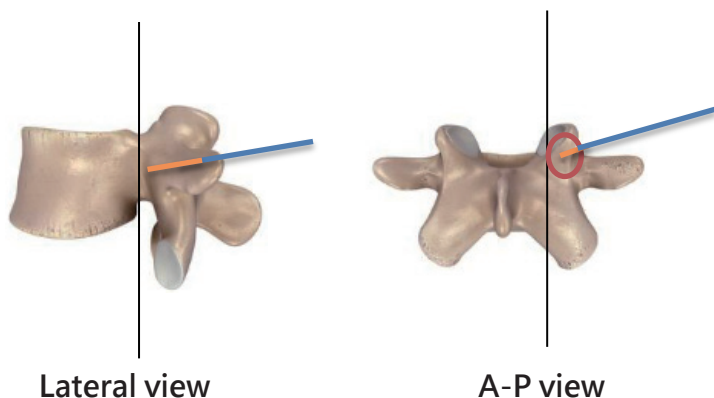
- The spinous process will be located just at the center point of the pedicle on both sides.
- Lateral view determines the surgical segment and angle (the endplate will present as a straight line).



- Under AP view display, locate the skin directly above pedicle and move laterally outward by about 1 cm or more depending on the patient's body shape, and then the trocar is inserted through the skin to the junction of facet joint and transverse process.



- The lateral view confirms the insert depth, and the AP view confirms the angle (when passing through the pedicle, the trajectory should be far away from the inner edge of the pedicle to avoid injury to the spinal cord).



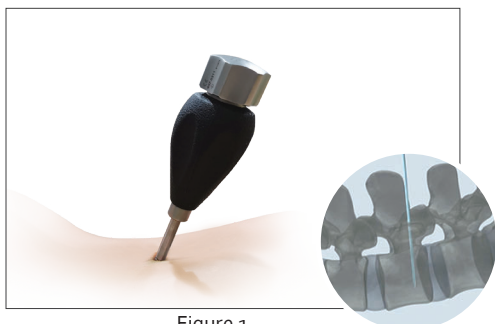


Figure 1

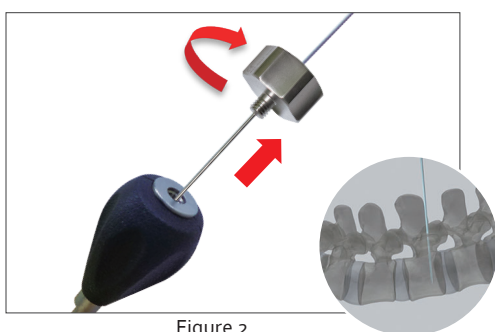


Figure 2

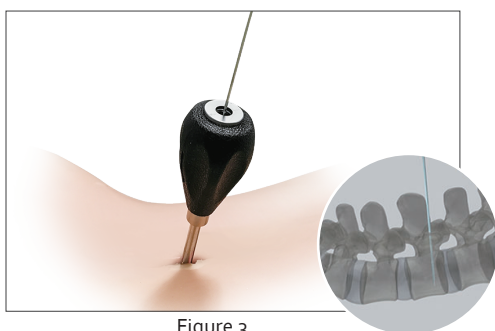


Figure 3

01 Guide Wire Placement (1/2)

A longitudinal incision about 1.5cm is made through the skin and fascia. Insert the **Threaded Awl (433-0201)** down to the surface of the pedicle and dock the tip on the bony anatomy of the desired level. (Fig. 1)

NOTE:

Use fluoroscopy to monitor the position during insertion

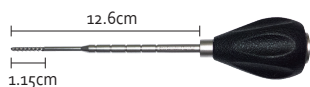
02 Guide Wire Placement (2/2)

Once proper placement is confirmed, remove the **Threaded Awl Needle (407-0311)**. (Fig. 2)

NOTE:

Use fluoroscopy to monitor the position during insertion

Insert the **Guide Wire (407-1106)** through the cannula and advance it just past the tip of the targeting. Use fluoroscopy to ensure the location of the Guidewire. After that, remove the Threaded Awl, and leave the Guide Wire in place. (Fig. 3)



433-0201

Threaded Awl



407-0311

Threaded Awl Needle



407-1106

Guide Wire

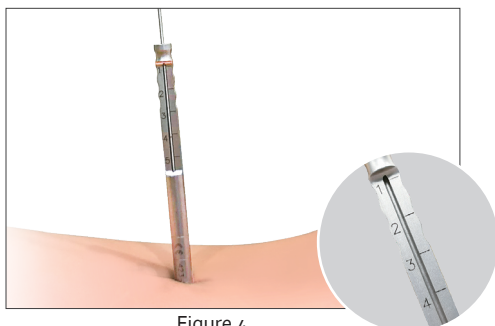


Figure 4



Figure 5

03 Tissue Dilation & Tapping (1/2)

Insert the **Small Dilator (423-7201)** over the **Guide Wire (407-1106)** until the tip reaches the pedicle entry point. The laser marking on the Guide Wire indicates its depth. (Fig. 4)

NOTE:

The Guide Wire must maintain in fixed position when insertion or removal of any instrument.

Please hold it in position so that it stays at the target site.

Use the dilator sequentially to dilate soft tissue of the path to the pedicle. Insert the **Middle Dilator (451-7202)** through the Small Dilator, and then remove the Small Dilator. (Fig. 5)

NOTE:

The fascia and muscle must be dilated to allow for screw placement.



423-7201

Small Dilator



451-7202

Middle Dilator

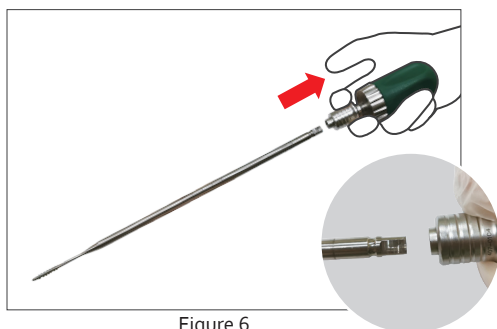


Figure 6

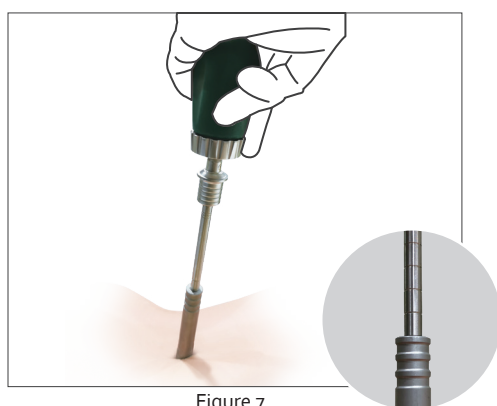


Figure 7



Figure 8



Figure 9

04 Tissue Dilation & Tapping (2/2)

Select the appropriate tap size and connect it with the **Ball Handle, Ratchet (407-0104)** or **T-Handle, Ratchet (433-0101)**. It is recommended to tap after introducing **Middle Dilator (451-7202)**. (Fig. 6,7)

NOTE:

The Guide Wire must maintain in fixed position when insertion or removal of any instrument.

Please hold it in position so that it stays at the target site.

After tapping, continue to dilate tissue with **Large Dilator (451-7203)**, and remove the **Middle Dilator (451-7202)**. (Fig. 8,9)

NOTE:

Keep the large dilator on the bone as much as possible to avoid soft tissue or muscle tissue from entering the channel.



433-0524~433-0527

Cannulated Cortex Tap



407-0104

Ball Handle, Ratchet



433-0101

T-Handle, Ratchet



451-7203

Large Dilator

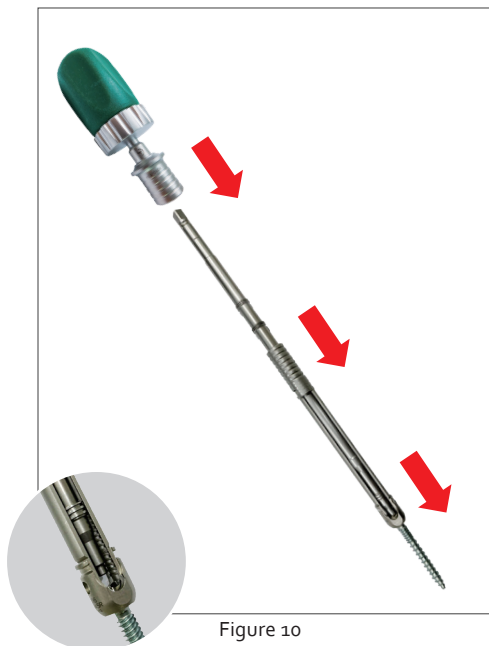


Figure 10

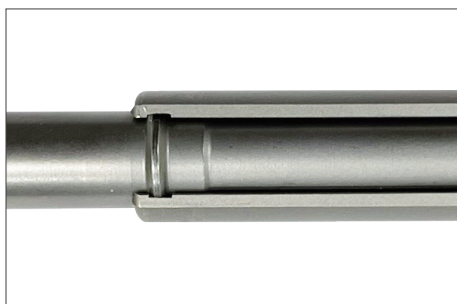


Figure 11

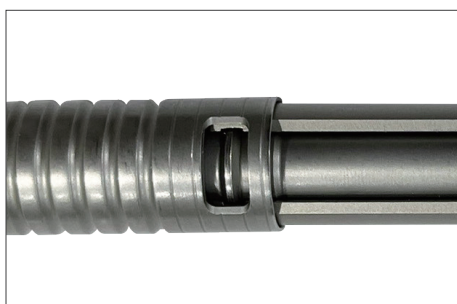


Figure 12

05 Assembly of Screw and Screwdriver

Attach the **Ball Handle, Ratchet (407-0104)** or **T-Handle, Ratchet (433-0101)** to the **Screwdriver (451-3301)**. Insert the Screwdriver into the Long Arm Tabs and rotate to engage the tip of the Screwdriver into the stardrive recess of the screw. (Fig. 10) Ensure the ring structure on the Screwdriver is attached to the proximal end of the Long Arm Tab (Fig. 11) and place the holder over them. (Fig. 12)

NOTE:

Use **Screw Remover (451-2201)** to remove or adjust the screw.



451-3301

Screwdriver

451-2201

Screw Remover



Figure 13



Figure 14

06 Screw Insertion

Insert the assembled **Screwdriver (451-3301)** over the **Guide Wire (407-1106)** into the pedicle. (Fig. 13)

Advance the screw to the desired depth and verify placement under fluoroscopy. (Fig. 14) After screw placement, remove the Guide Wire, **Large Dilator (451-7203)** and Screwdriver from the screw.

Repeat the steps above to place the second screw at the adjacent operable level.



451-3301

Screwdriver

407-1106

Guide Wire



451-7203

Large Dilator



Figure 15



Figure 16

07 Rod Measurement

Insert the **Rod Measure (423-4802)** down to the bottom of the screw head and determine the length of the ASA MIS Pre Bent Rod or ASA MIS Rod.

Make sure that the front end of Rod Measure is completely placed in the screw head. Since the length of the pre-extended part has been considered, please select the corresponding rod according to the measurement data. If the value is in between two numbers, please select the longer size. (Fig. 15,16)



428-4802

Rod Measure



Figure 17

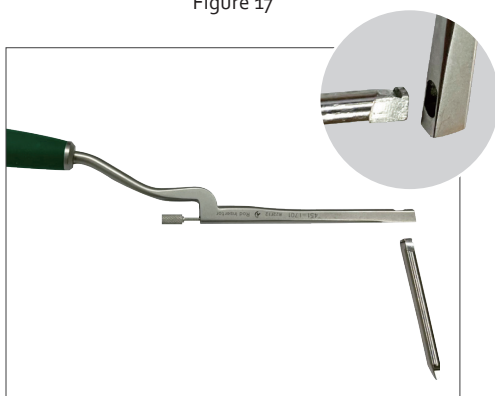


Figure 18



Figure 19

08 Rod Preparation and Insertion (1/2)

The rod can be brought into the suitable shape by using **Rod Bender (406-1201)**. Do not apply reverse bending to a pre-bent rod, as this may weaken the final construct. (Fig. 17)

Assemble the square end of the rod into the **Rod Insertor (451-1701)** and use the **Rod Insertor Screwdriver (451-3303)** to secure the rod firmly. (Fig. 18,19)



406-1201

Rod Bender
(french bender)



451-1701

Rod Insertor



451-3303

Rod Insertor Screwdriver



Figure 20

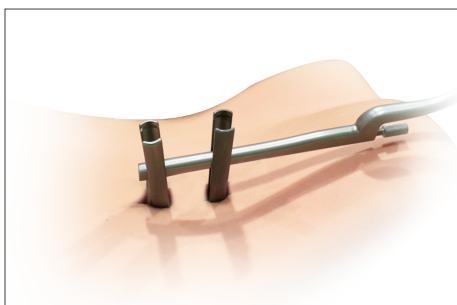


Figure 21

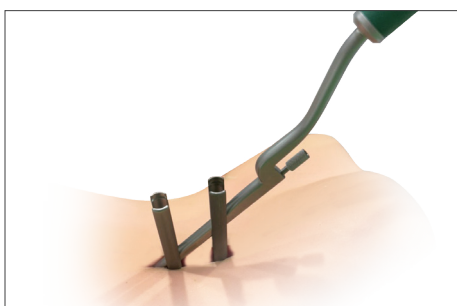


Figure 22

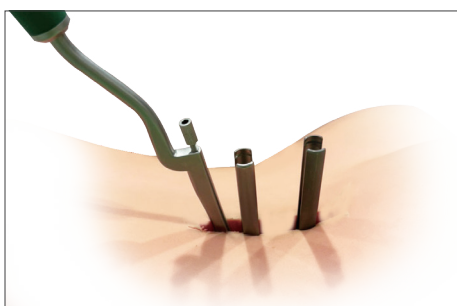


Figure 23

09 Rod Preparation and Insertion (2/2)

- Align the slots of the Long Arm Tabs so that they are in line with each other to allow passage of the rod.
- Position the **Rod Inserter (451-1701)** parallel to the skin's surface with the tip of the rod facing downward. (Fig. 20)
- Insert the Rod cranially to caudally. The entire rod should be contained within the Long Arm Tabs.
- Use the Rod Inserter to align the Long Arm Tabs until they are paralleled with one another. (Fig. 21)
- Advance the distal end of the rod towards the screw and down the bottom portion of the Long Arm Tabs until it touches the top of the screw head or is as deep as the tissue allows. It is necessary for the distal end of the rod to be below the fascia before proceeding. (Fig. 22)
- Twist the Long Arm Tabs to verify whether the rod has successfully passed through the screw. If the tabs are still rotatable, it means the rod is not contained within the tabs. Rod placement should be re-attempted. (Fig. 23)
- Verify adequate rod overhang at each end of the construct with fluoroscopy.

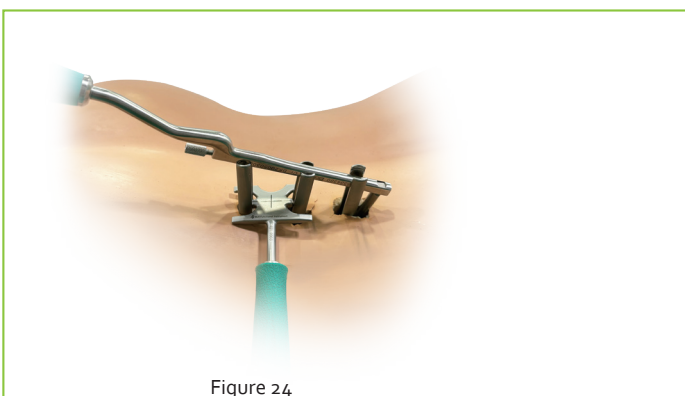


Figure 24

Multifunctional Instrument

Place the **Multifunctional Instrument (451-0903)** between the Long Arm Tabs to align the openings of the screws and facilitate easy passing of the rod. (Fig. 24)



451-0903

Multifunctional Instrument

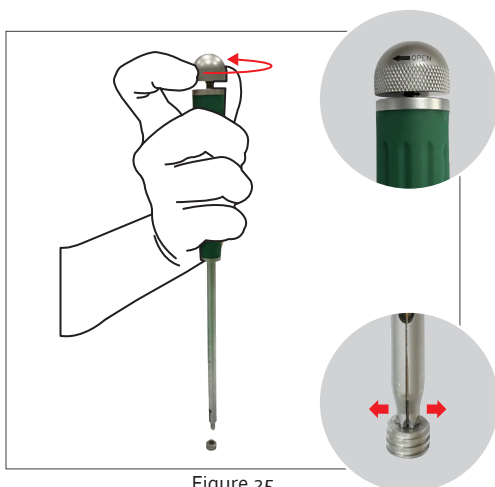


Figure 25

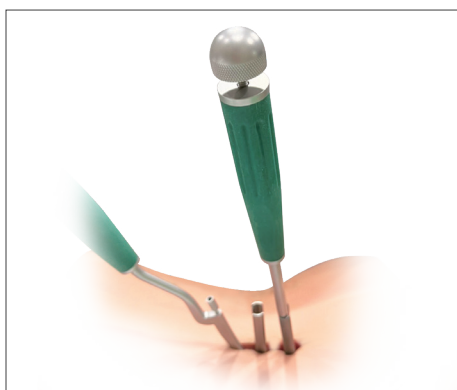


Figure 26

10 Set Screw Insertion and Rod Inserter Removal

The shaft of the **Star Set Screw Holder (451-1301)** can control the size of the tip. Rotate the shaft clockwise to reduce the volume of the tip, which is convenient for attachment of the set screw, and then rotate counterclockwise to enlarge the tip volume to hold the set screw. (Fig. 25)

Insert the set screw by using Star Set Screw Holder and fixed firmly with **Star Set Screwdriver (451-3302)**. Remove the **Rod Inserter (451-1701)** when the rod is completely fixed. (Fig. 26)

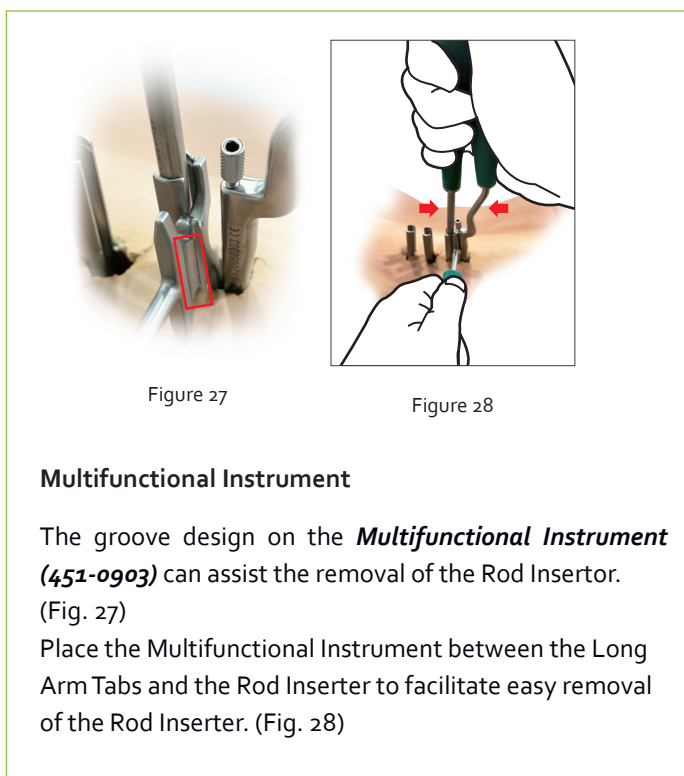


Figure 27

Figure 28

Multifunctional Instrument

The groove design on the **Multifunctional Instrument (451-0903)** can assist the removal of the Rod Inserter. (Fig. 27)

Place the Multifunctional Instrument between the Long Arm Tabs and the Rod Inserter to facilitate easy removal of the Rod Inserter. (Fig. 28)



451-1301

Star Set Screw Holder



451-3302

Star Set Screwdriver



451-1701

Rod Inserter



451-0903

Multifunctional Instrument



Figure 29

11 Compression and Distraction

Introduce a **Star Set Screwdriver (451-3302)** into the implant and place a **Tab Breaker Wrench (451-8701)** over the Long Arm Tabs, ensuring the notches are seated on the rod. Next, position the **Compressor (451-0901)** around the Tab Breaker Wrenches where compression force will be applied. Place the **Multifunctional Instrument (451-0903)** between the Star Set Screwdrivers to serve as a fulcrum, making sure the Compressor is located underneath the Multifunctional Instrument. Finally, compress and tighten the set screw. (Fig. 29)

As for Distraction, the Compressor is placed above the Multifunctional Instrument. Distract and tighten the set screw.



451-0901

Compressor



451-0903

Multifunctional Instrument



451-1301

Star Set Screw Holder



451-3302

Star Set Screwdriver



Figure 30

12 Final Tightening

Tightening the set screw by using **Torque Limiting T-Handle (451-1001)** which is 10 N·m and **Star Set Screwdriver (451-3302)** to avoid damaging the implant.

To secure final tightening, place the **Tab Breaker Wrench (451-8701)** or **Counter Torque Wrench (451-3401)** over the Long Arm Tab(s) and ensure the notches are seated on the rod. (Fig. 30)

Introducing the Star Set Screwdriver into set screw, and then turn it clockwise until an audible click is heard. (Fig. 31)



Figure 31



451-1001

Torque Limiting
T-Handle



451-3302

Star Set Screwdriver



451-8701

Tab Breaker Wrench



451-3401

Counter Torque Wrench



Figure 32

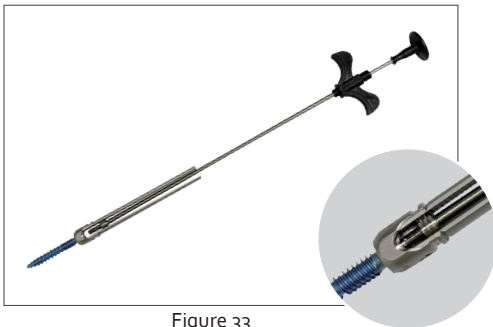


Figure 33

13 Final Tab Removal

Place the **Tab Breaker Wrench (451-8701)** over the Long Arm Tab and ensure the notches are seated on the rod. Slide the **Tab Breaker (451-8601)** over the Long Arm Tab and break it off. (Fig. 32) Remove the Long Arm Tab from the surgical site. Repeat the procedure on the second Long Arm Tab.

14 Cement Augmentation (Optional)

Insert the **Introducer (451-1401)** into the Long Arm Tabs and thread it into the screw head while holding the Long Arm Tabs to provide counter torque. This aligns the screw part to the screw head. (Fig. 33)

Prepare the cement according to the instructions and draw it into the syringe. The syringe is secured to the Introducer via the Luer Lock. Then, apply the cement into the screw.

Remove the Introducer after cement has been delivered.

NOTE:

The Introducer is removed after the cement has reached an appropriate viscosity to prevent leakage.



451-8601

Tab Breaker



451-8701

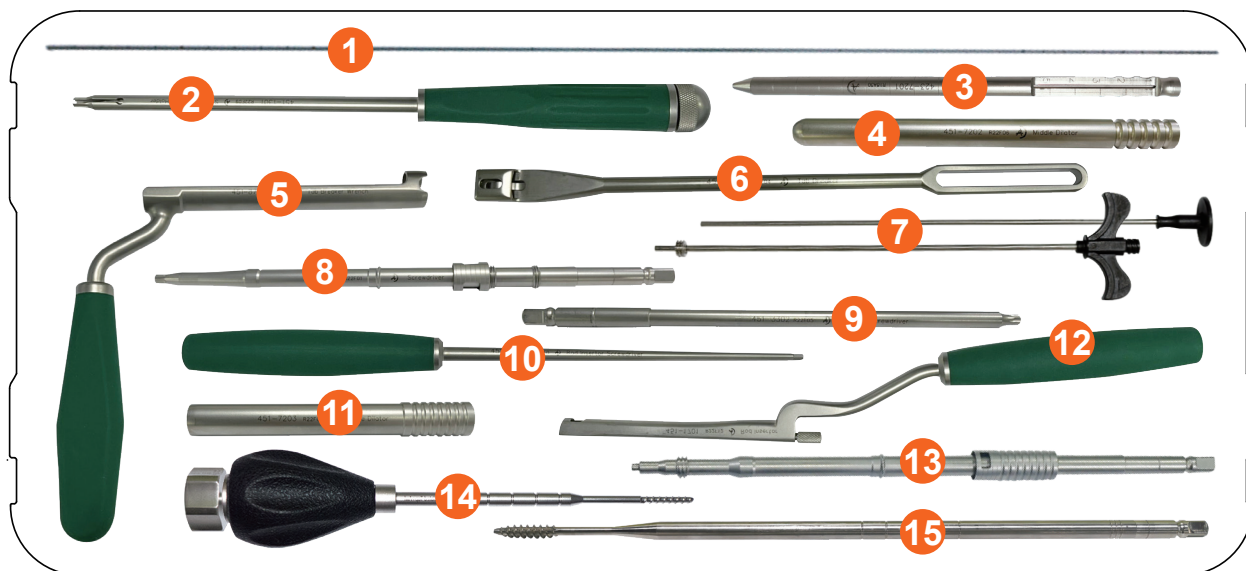
Tab Breaker Wrench



451-1401

Introducer

Instrument Set

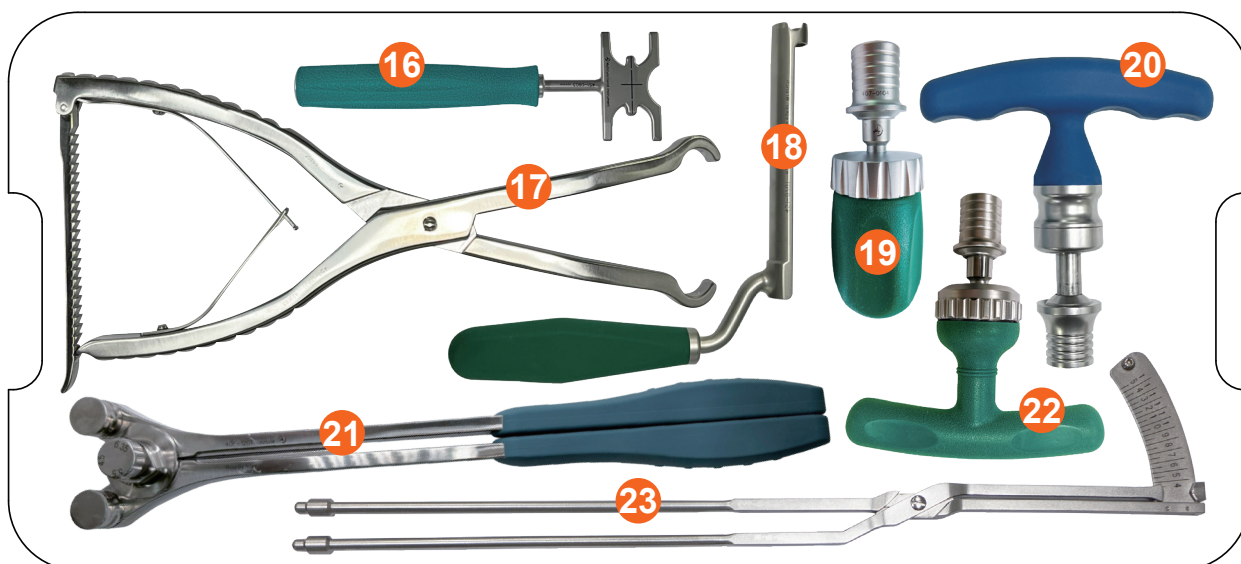


Instrument Tray 1

Cat.No.	Description	Q'nty
① 407-1105	Guide Wire(450mm)	*
407-1106	Guide Wire(500mm)	8
② 451-1301	Star Set Screw Holder	2
③ 423-7201	Small Dilator	1
④ 451-7202	Middle Dilator	1
⑤ 451-8701	Tab Breaker Wrench	1
⑥ 451-8601	Tab Breaker	2
⑦ 451-1401	Introducer	*
⑧ 451-2201	Screw Remover	1
⑨ 451-3302	Star Set Screwdriver	2

* Optional

Cat.No.	Description	Q'nty
⑩ 451-3303	Rod Insertor Screwdriver	1
⑪ 451-7203	Large Dilator	1
⑫ 451-1701	Rod Insertor	1
⑬ 451-3301	Screwdriver	2
⑭ 433-0201	Threaded Awl	1
407-0311	Threaded Awl Needle	1
⑮ 433-0524	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



Instrument Tray 2

Cat.No.	Description	Q'nty
16 451-0903	Multifunctional Instrument	1
17 451-0901	Compressor	1
18 451-8701	Tab Breaker Wrench	1
19 407-0104	Ball Handle, Ratchet	1
20 451-1001	Torque Limiting T-Handle	1
21 406-1201	Rod Bender (french bender)	1
22 433-0101	T-Handle, Ratchet	1
23 423-4802	Rod Measure	1

* Optional

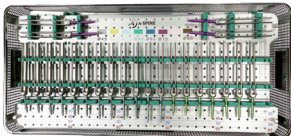
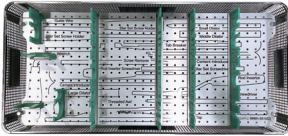
Instruments

Cat.No.	Description	
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	
423-4802	Rod Measure	
423-7201	Small Dilator	
433-0101	T-Handle, Ratchet	
433-0201	Threaded Awl	
433-0524 433-0525 433-0526 433-0527	4mm Cannulated Cortex Tap 5mm Cannulated Cortex Tap 6mm Cannulated Cortex Tap 7mm Cannulated Cortex Tap	
451-0901	Compressor	

* Optional

Cat.No.	Description	
451-0902	Distraction*	
451-0903	Multifunctional Instrument	
451-1001	Torque Limiting T-Handle	
451-1301	Star Set Screw Holder	
451-1401	Introducer*	
451-1701	Rod Insertor	
451-2201	Screw Remover	
451-3301	Screwdriver	
451-3302	Star Set Screwdriver	
451-3303	Rod Insertor Screwdriver	
451-3401	Counter Torque Wrench*	

* Optional

Cat.No.	Description	
451-7202	Middle Dilator	
451-7203	Large Dilator	
451-8601	Tab Breaker	
451-8701	Tab Breaker Wrench	
99900-051	ASA Product Case	
99901-051	ASA Instrument Case	

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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