

# MikoII 5.5 Minimal Invasive Screw-Rod System



# Why choose Fule?

## Fule advantage

- Beijing Fule is a national high-tech enterprise integrating R&D, production and sales of medical equipment, and has a production line of fully intelligent processing equipment
- The academician expert studio was established to help Fule improve its research and development capabilities, and further deepen the cooperation of production-academy-research; it was approved as a post-doctoral research station
- The hardware facilities are complete, the R&D team is excellent, and the clinical experts work closely with more than one hundred domestic and foreign patents..
- Based on the agent cooperation model , it has established a nationwide sales and service network and its products are supplied to nearly a thousand tertiary hospitals across the country and exported to more than 20 overseas countries.

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Beijing Fule Science & Technology Development Co., Ltd

Add: No. 50, Mafang West Industry Zone, Pinggu District, Beijing 101204, China

## Product Advantage

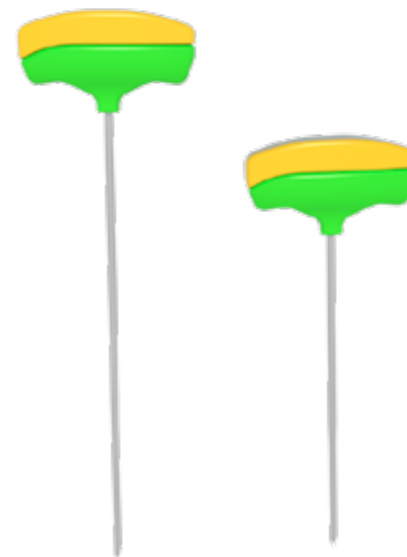


- Lower profile (1mm) and Smaller sizes 30% than VSS system screws



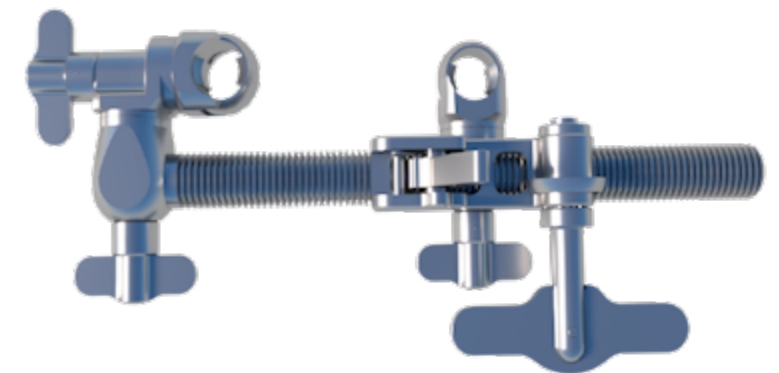
- Connected with screw shrapnel card, easy to disassemble.

## Product Advantae

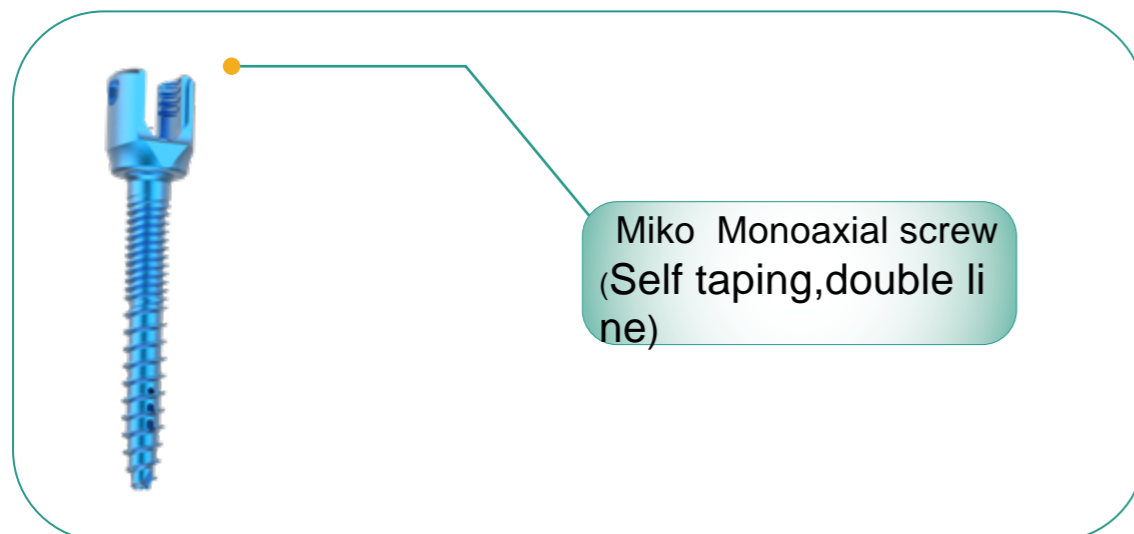
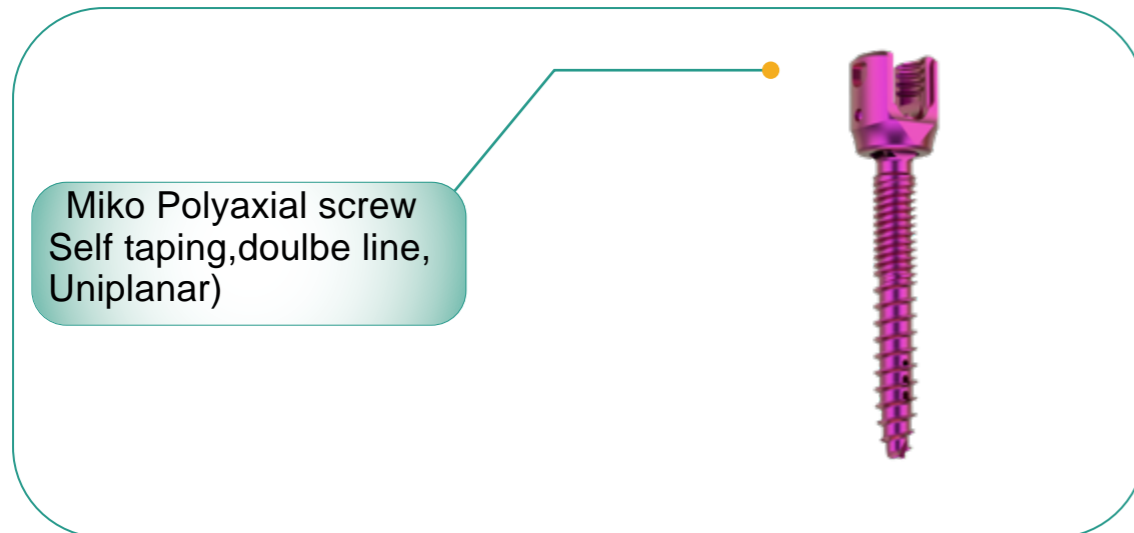
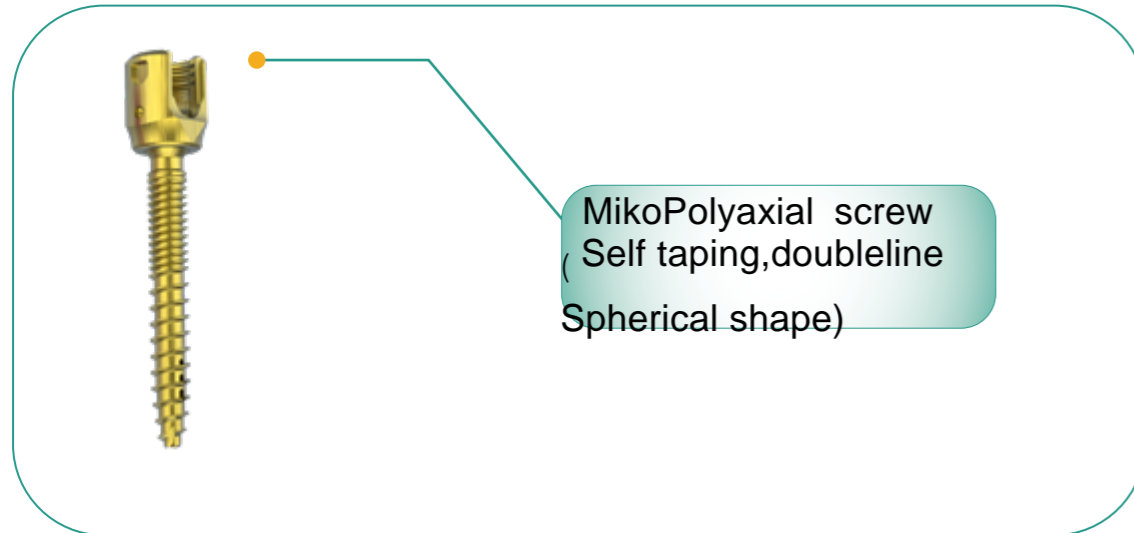


- Needle sizes are optional with long and short one.

- One key conversion between distract and compress



## Product Advantage



## Instructions

- **【Indication】**

Lumbar disc herniation; Lumbar spondylolisthesis;  
Lumbar instability; Lumbar spinal stenosis.

- **【Contraindication】**

Elderly patients with severe heart and lung disease;  
Patients with severe osteoporosis;  
Patients with significant lumbar or thoracolumbar scoliosis;  
Patients with pedicle dysplasia;  
Patients with unclear preoperative localization;  
Isthmus fissure;  
Vertebral spondylolisthesis II degree or above.

## Surgical Steps

### Step 1 Position preparation, body surface positioning

- This operation requires the help of a fluoroscopy or navigation system Assisted completion, so the patient is prone in see-through
- On the operating bed, ensure complete fluoroscopy of the anteroposterior and lateral positions (FIG1a)
- Firstly, the patient can achieve partial or complete reduction of the fractured vertebra through postural adjustment after anesthesia.
- Determine the surface location of the pedicle for puncture (Figure 1b).



FIG 1a

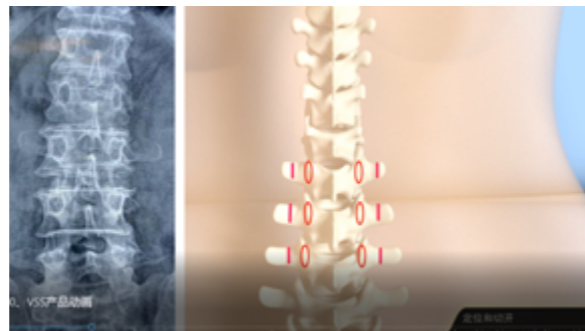


FIG 1b

## Surgical Steps

### Step 2 Prepuncture

- The location of the incision was determined by prepuncture. The location of the puncture point was the vertebral arch 1 -- 1.5CM outside of the root surface site, an obese patient's approach needs to be more lateral (FIG. 2a).
- Puncture diagram. ( FIG 2b).

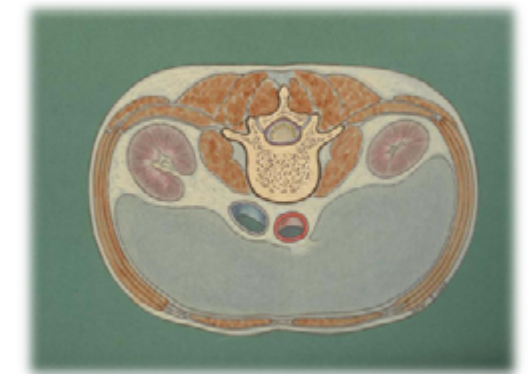


FIG 2a

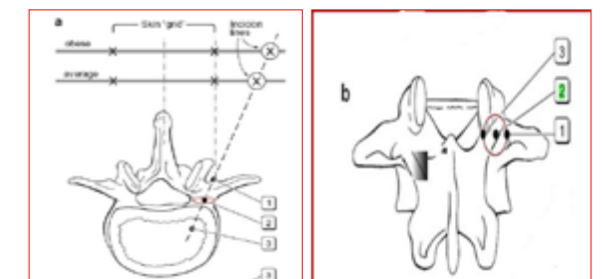


FIG 2b

## Surgical Steps

### Step 3 Incision

- Local infiltration of epinephrine saline at the incision site (Figure 3a)
- A 1.5CM incision was made to incise the skin and fascia (Figure 3b)



图 3a

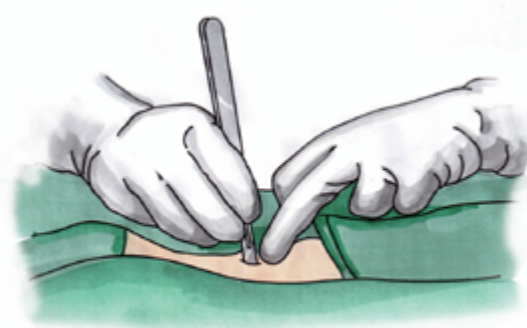


图 3b

## Surgical steps

### 【Step 4 Positioning guide puncture device placement

- Insert the positioning guide piercer through the insertion process fluoroscopy confirms the position and orientation of the positioning guide piercer insertion (Figure 4a).
- The orientation is guided by anteroposterior X-ray perspective Positioning guide 10 ~ 15° parallel endplate puncture into the vertebra. The puncture tip is placed on the outer edge of the vertebral arch root projection. (i.e.9-10 point on the left side, 2-3 point on the right side), leaning inward positioning guide 6-10mm into the bone through the piercing. The tip of the position-guided puncture device did not break through the medial cortex in the pedicle projection (Figure 4b).

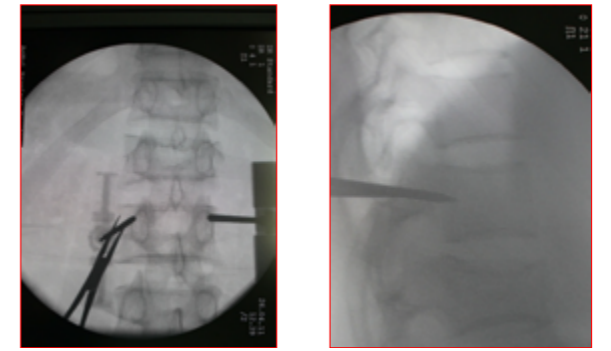


图 4a

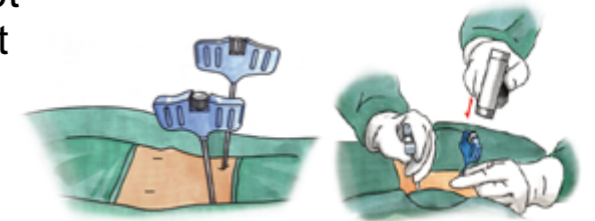


图 4a

## Surgical Steps

### Step 5 Positioning needle placement

- The bone positioning needle is inserted into the puncture needle. Bone positioning needle should be superimposed 35-40mm of puncture needle has been obtained for osseous fixation (FIG 5a). Bone positioning needle should be a little deeper than the tap (hollow).

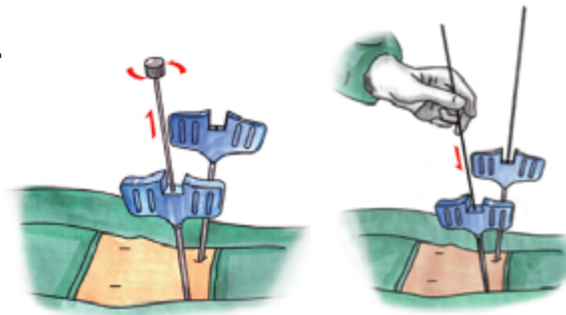


FIG 5a

When the bone locator needle reached the desired depth, the locator puncture device was removed (Figure 5b).

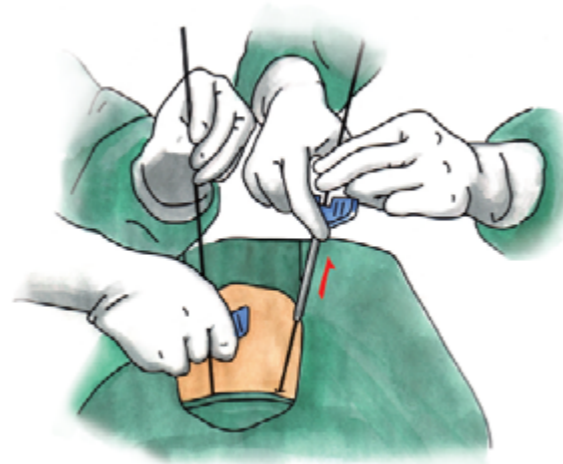


FIG 5b

## Surgical steps

### Step6 Preparation for the pedicle approach

- The sleeve (I) was first placed over the bone positioning needle and inserted into the bone surface, and then into the sleeve (II), sleeve (I I I). When sleeve (I I), sleeve (I I I) position are ready, the sleeve (I) is removed (FIG 6a).
- Along the bone positioning needle is inserted into the bone drill (hollow), which was dilated at the cortical bone (Figure 6b).
- Select a suitable tap (hollow) for tapping. Pay attention to the depth of the tap, do not over twist rotatio and note the depth of the tap (Figure 6c).



FIG 6a

Along the bone positioning needle is inserted into the bone drill (hollow), which was dilated at the cortical bone (Figure 6b).

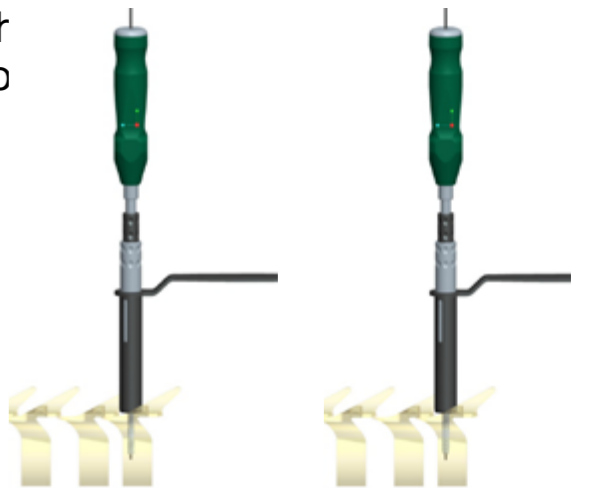


FIG 6b

FIG 6c

Note that the bone positioning needle cannot follow the wire to move forward to anterior vertebra when awling or tapping.

## Surgical Steps

### Step 7 Implant pedicle screw

- Select the appropriate length and diameter of the pedicle screw, through the positioning needle was inserted and the pedicle screw position was confirmed by fluoroscopic monitoring.
- 

After the screw was inserted, the pedicle nail wrench and the guide needle were removed.



FIG 7a

## Surgical Steps

### Step 8 Measure the length of Rod

- Read the data from the bone gauge and select the appropriate connecting rod.

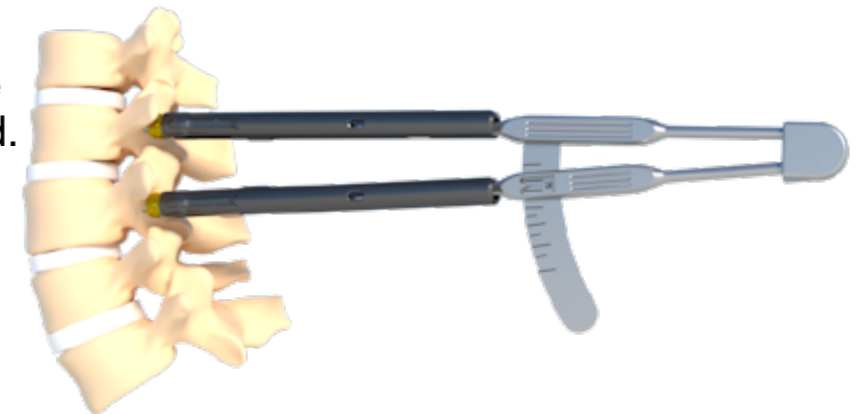


FIG 8b

### 【Step8】 Rod connected with holder

- Select the appropriate rod and insert the end of the rod into the small hole of the holder.
- Insert the driver into the hexagonal hole of the holder and rotate the driver until the rod is held tightly.



FIG 8a

## Surgical Steps

### Step 9 Place Rod

- According to arrow direction, Align the the rod and connector, then put it down until it touches the tail of the screw or until the head of the rod needs to be located under the fascia (Figure 9a).

- Rotate the holder 90 degrees. This step will guide the rod to enter the bottom notch of the connector. To check if the rod in placement position in the bottom notch of the connector through Intraoperative fluoroscopy (Figure 9b).

If the radian of the rod does not meet the expected requirements, we are equipped with a special rod bender to ensure that the pre-bending direction corresponds to the position of the groove held by the rod holder (FIG. 9C).

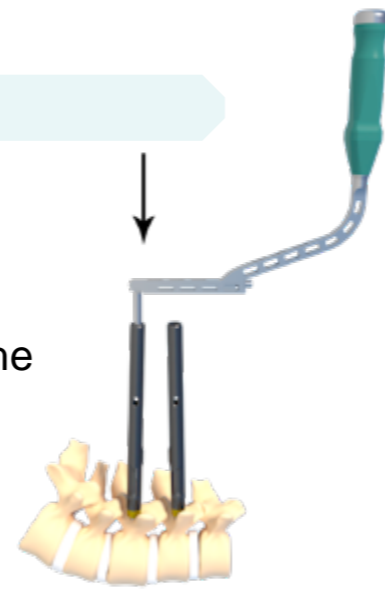


FIG 9a

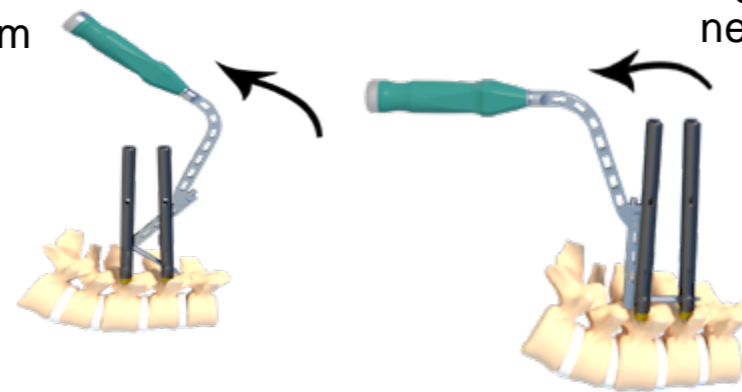


FIG 9b



FIG 9c

## Surgical Steps

### Step 10 Preload and lock the screw

- Confirm that the rod is located on the screw of the long tail slot by fluoroscopy or a small miniature retractor, you can use the driver to preload and lock the screw (FIG.10a)
- In order to achieve the distraction, compression when the vertebral body does not rotate and Height is missing and one end plug needs to be locked (Figure 10b).

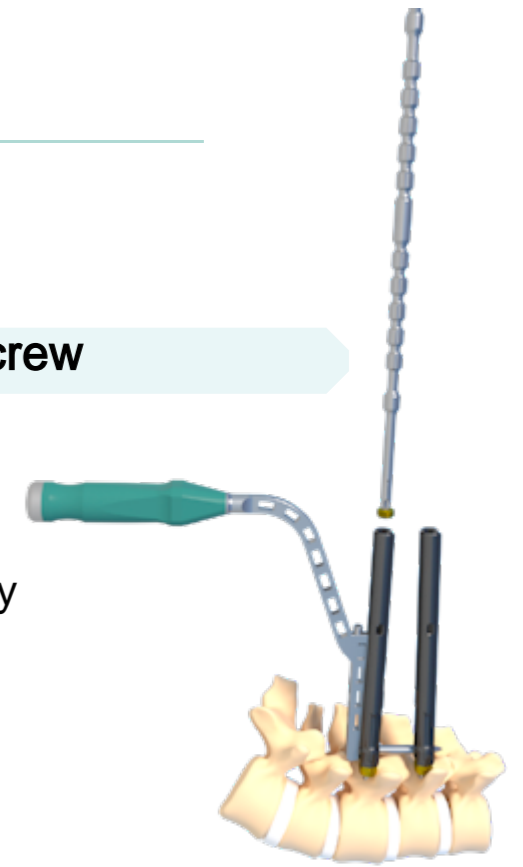


FIG 10a



FIG 10b

## Surgical Steps

### Step 11 Distract, Compression and Final lock

Spinal distractor can be used to distract and compress at the same time.

- The polyaxial angle can be realized between the two rotating sleeves, which can be well adapted to the distraction and compression of the pedicle screw.

Adjust the angle of the rotary sleeve according to the angle and position of the pedicle screw to be distracted or compressed, and load from the top of the sleeve to the bottom (Figure 11a)

- The vertebral body distractor was inserted into the upper of the connector.

Then, in the distracted state, tighten the plug (FIG. 11b).

- Use wrench to finally lock all plugs into the connecting rod (Figure 11c)

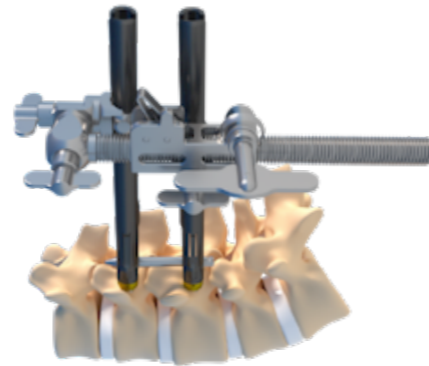


FIG 11a

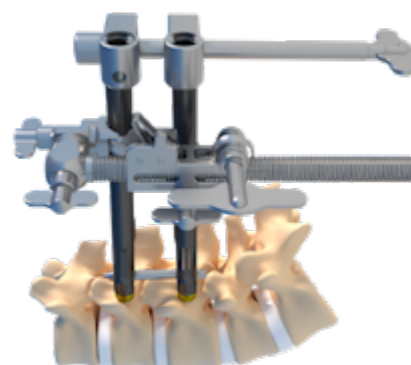


FIG 11b



FIG 11c

## Surgical Steps

### Step 12 Remove the connector, suture

- Insert distractor into the connector and press, make the connector break away and bring it out (FIG. 12).

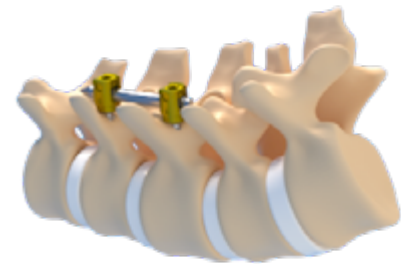
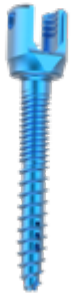


FIG 12

- After connectors were removed, the wound was sutured.

## 产品信息

### Mik monoaxial screw)



		螺钉长度 (mm)					
		30	35	40	45	50	55
螺钉直径 (mm)	5.0		*	*			
	5.5		*	*	*		
	6.0		*	*	*	*	
	6.5		*	*	*	*	*
	7.0	*	*	*	*		

### Miko polyaxial Uniplanar)



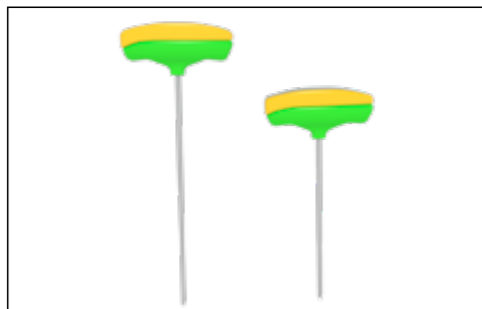
		螺钉长度 (mm)					
		30	35	40	45	50	55
螺钉直径 (mm)	5.0		*	*			
	5.5		*	*	*		
	6.0		*	*	*	*	
	6.5		*	*	*	*	*
	7.0	*	*	*	*		

### Miko Polyaxial(Spherical-shape)



		螺钉长度 (mm)					
		30	35	40	45	50	55
螺钉直径 (mm)	5.0		*	*			
	5.5		*	*	*		
	6.0		*	*	*	*	
	6.5		*	*	*	*	*
	7.0	*	*	*	*		

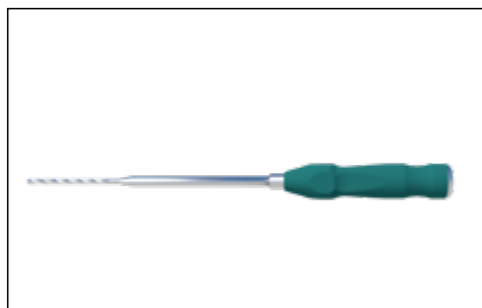
## Instrument



1420018/19 Guided puncture device



1420020 Positioning Needle ( )



110037 Drill ( Cannulated )

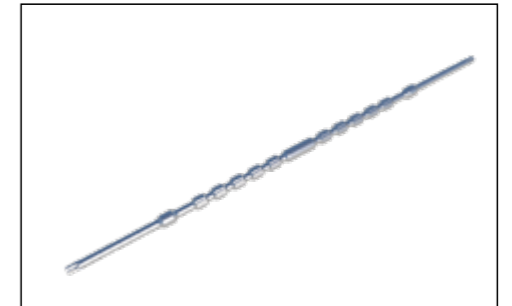


1110002 Tap ( II ) 6.0

## 器械信息



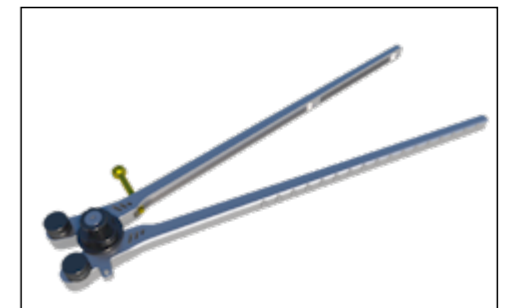
1040024 Handle ( III )



1040043 Wrench ( Preload )



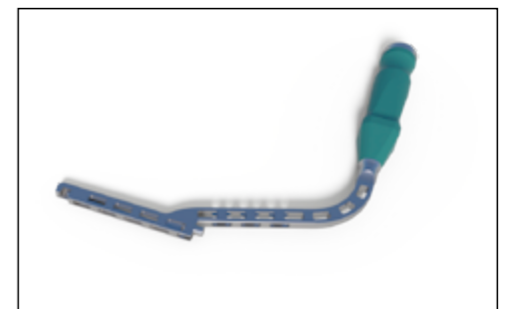
110-420 Hammer



1040031 Rod bender



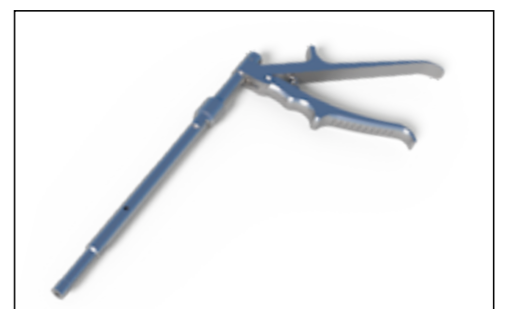
1420002Screwdriver(XXVIII )



1420004 Rod Holder



1420007 Counter wrench



1420010 Screw holder

Instrument information



110116 Sleeve



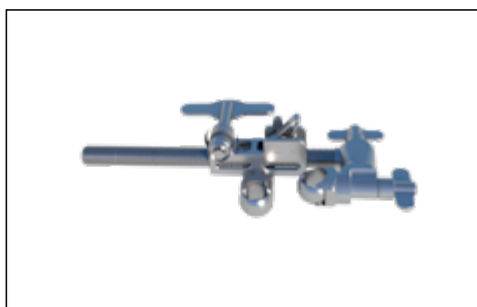
110117 Sleeve



110118 Sleeve



1040042 Wrench(Trox quick changed)



1420001 Distractor ( II )



1420011 Distractor

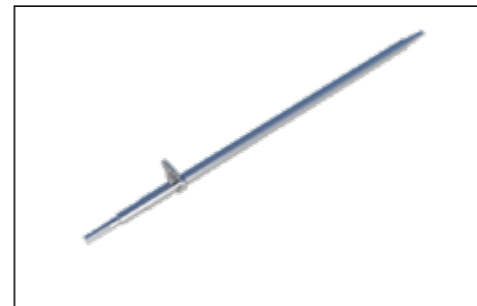


1420006 Sleeve



110452 Wrench for screw plug

Instrument information



1040045 Wrench(Trox)



1420005 Sleeve(VI)



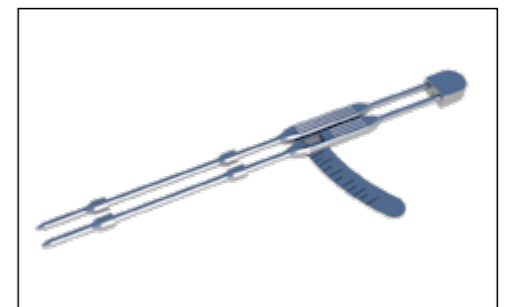
113-441 Torque limit handle



1420003 Holder



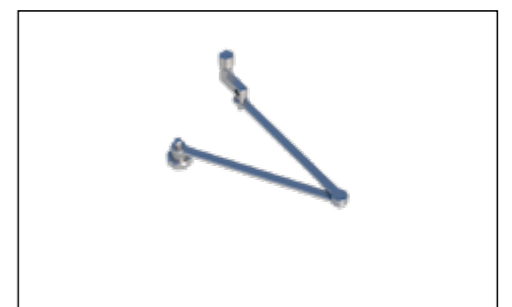
1420008 Ratchet handle



1420009 Measurer



1420016 Wrench(XXI)



1420017 Fixator( I )