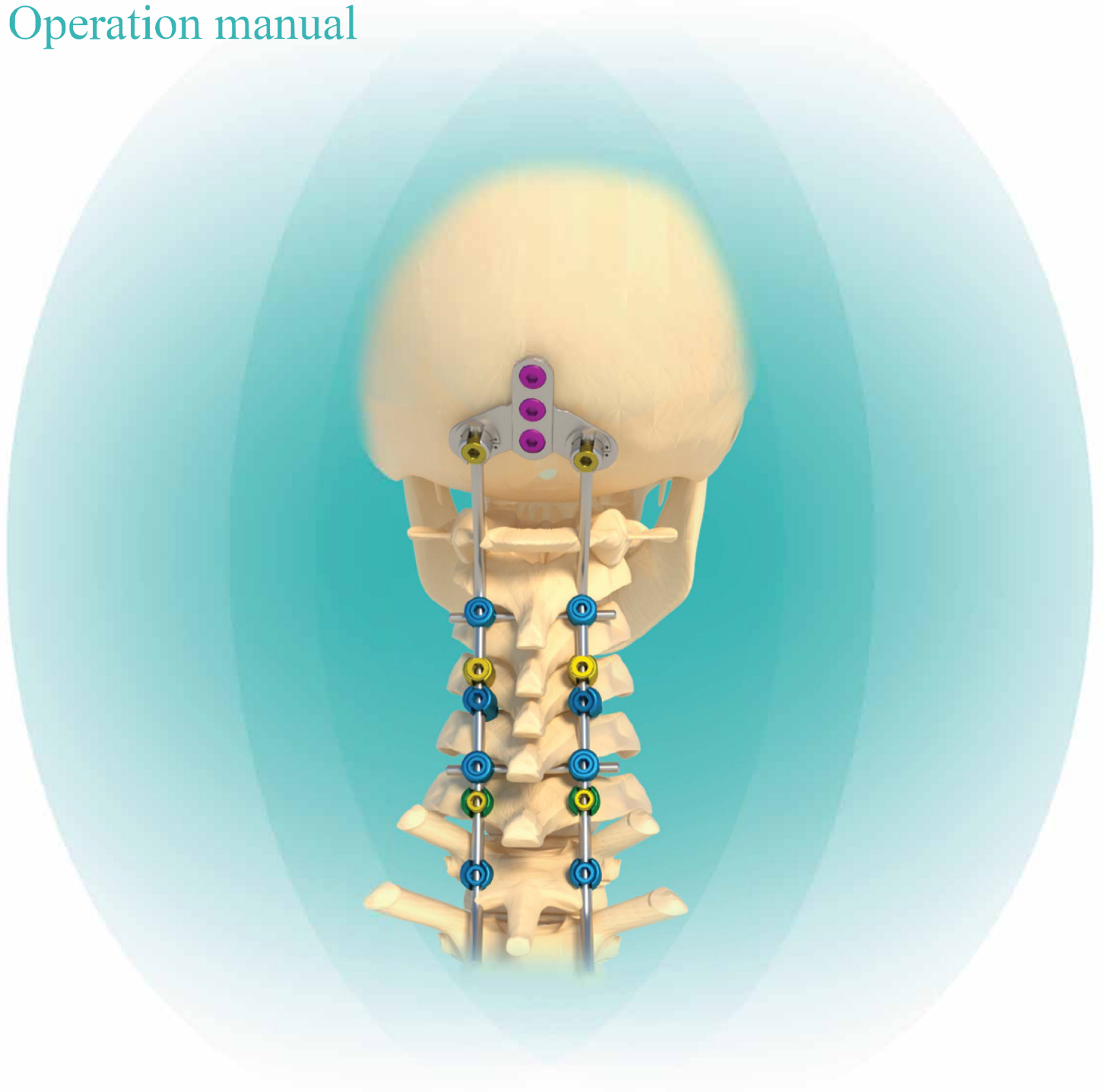


# CFS Posterior Spinal Screw Rod System

Operation manual





# Why Choose Fule?

## Our Advantages

● The company is a national high-tech enterprise integrating research and development, production and sales of medical devices, with a full intelligent processing equipment production line.

● Academician expert studio was established to help improve Fule's R&D capability and further deepen industry- academic- research cooperation; Approved postdoctoral research workstation.

● With complete hardware facilities, excellent R & D team, close cooperation with clinical experts and more than 100 patents at home and abroad.

● Based on the agent cooperation mode, a sales service network covering the whole country has been established. The products are supplied to nearly 1000 third class hospitals in China and exported to more than 20 overseas countries.



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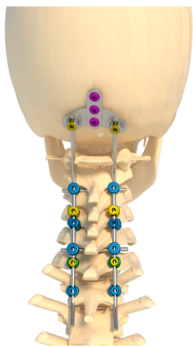
E-mail: YXSC@fulekeji.com



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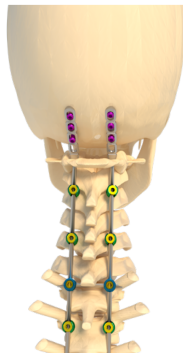
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## Product advantages



1

Occipital titanium plate



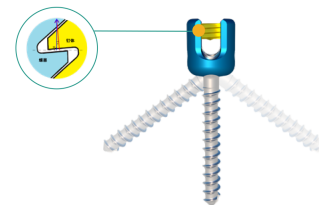
2

Occipital-cervical connecting rod

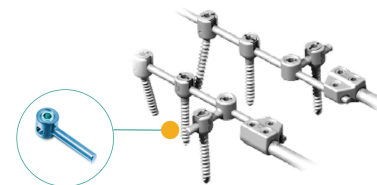
- Different occipital fixation methods can be selected.
- The notch is lower with the 3.5mm diameter rod
- A variety of instruments can be selected to suit different clinical habits.

## Product advantages

- Low residential notch produces less stimulation to surrounding soft tissue that improve the comfort to patient.
- Negative angle threads design can effectively prevent the screw from expanding.
- Special polyaxial screw design, the maximum angle can reach  $55^\circ$



- The shifter facilitates the non-linear arranged screws to install.



## Instruction

### ● 【Indication】

Instability of occipitocervical and upper cervical spine;

Degeneration or abnormal after trauma of lower cervical spine;

Instability of lower cervical spine;

When the anterior fusion needs the posterior stabilization.

## Surgical procedure

The operation procedure is only for reference and has no guiding effect.

### 【Step 1】 Expose

- The patient was placed in prone position, and a standard posterior cervical median incision was applied.
- Expose occipital bone, posterior arch of atlas, and lateral mass and vertebral arch of cervical vertebrae to be fused.



## Surgical procedure

### 【Step 2】 Cortical opening

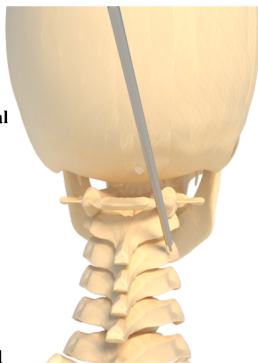
- After the screw insertion point and angle are determined, the cortical bone is broken with an open drill, and the hole was reamed with an expanding awl.

Annotations---- Implant cervical screws:

#### (1) C3-C7 unilateral segmental posterior internal fixation

The screw entry point is 2mm inward and upward at the midpoint of the unilateral vertebral segment. The screw entry angle is inclined outward by 20°-25° and upward 30°-40°. The screw is paralleled to the adjacent articular surface and aligned forward above the anterolateral angle of the upper articular process. In order to facilitate the screw to be placed accurately, inserting a thin scalpel to verify the point on the articular surface is located.

Proper screw placement minimizes the risk of vertebral artery and nerve injury, and provides maximum screw length and optimal fixation.



## Surgical procedure

### 【Step 2】 Cortical opening

#### (2) C3-C7 Posterior pedicle fixation fixation

The screw entry point is 2-5mm inside the edge of the lateral mass, 2-3mm below the articular surface base of the upper articular process. The screw entry angle is 30°-45° from the coronal plane, and parallels to the upper endplate from sagittal plane.

During the drilling, the probe assists to explore bottom and surroundings carefully for conforming whether it is able to be continued.

## Surgical procedure

### 【 Step 2】 Cortical opening

- **C1-C2 posterior fixation**

C1 lateral mass screw entry - the screw entry point is 18-20mm away from the midpoint of the posterior tubercle of the atlas. The intersection with the lower edge of the posterior arch 2mm upward is the screw entry point. The direction of the screw path is vertical to the coronal plane. The angle of screw on the sagittal plane is 5° inclined to the head and the insertion depth is controlled at about 28mm.

C2 pedicle screw insertion - the screw insertion point is at the focus of the vertical line in the middle of the lateral mass. The screw is inclined to the head side by 25°, to the midline by 15°-25°, and the depth is generally controlled at about 24-26mm.

#### Tips:

Many domestic and foreign literatures have formed a variety of technical methods based on different academic views on the screw entry point, entry angle, depth and other information of the above approaches. We just select one of these technologies for common sense introduction. Doctors can make their own choices or refer to professional literature according to their own experience and habits.

On the other hand, because the differences in individual, gender and nature of the disease will lead to inconsistencies in the anatomy of the pedicle and its surrounding areas, we recommend that the patient should have a detailed imaging examination before operation.

## Surgical procedure

### 【 Step 3】 Create a trajectory



- The drill and the drill guide are used for drilling. Before that, the depth of trajectory can be determined, then the guide can be adjusted to the corresponding scale to limit the depth.
- If the bone is hard, thread with a tap.

## Surgical procedure

### 【 Step 4 】 Measure the depth of trajectory

- The depth of the trajectory shall be measured with a depth gauge, and the screws with appropriate length shall be selected.

## Surgical procedure

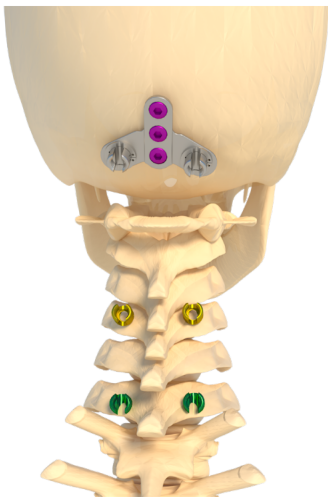
### 【 Step 5 】 Implant cervical screws

- Screw insetion shall be performed with a screw hex-wrench.
- Screw holding method: first insert the hexagon of the wrench into the screw head, then advance in the locking sleeve to implant the screw.



## Surgical procedure

### 【Step 6】 Measure the depth of trajectory



## Surgical procedure

### 【Step 7】 Pre-bend template, bend and cut rod

- Select a template of appropriate length and pre-bend it to adapt to the anatomical curvature of the patient.
- The rod is cut and pre-bent according to the movement of the template, so as to adapt to the sagittal bending of the spine. Excessive repeated bending of the rod should be avoided as far as possible to ensure the integrity of the material. Before implantation, the rod should be carefully checked for any damage.

Bending standard:

1. One end can be conveniently put into the U-shaped groove of each screw, and the other end can be attached to the surface of occipital bone.
2. Both occipital bones should be as close to the central line of occipital bone (the thickest part of bone).

## Surgical procedure

### 【Step 8】 Implant rod

- The rod is inserted into the U-shaped groove of the screw. During the insertion, the main process is to press the rod. There are three ways to achieve:

#### Method 1:

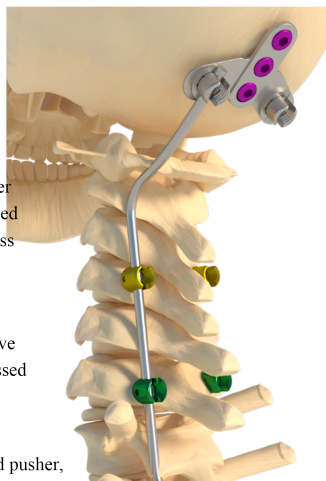
The half ring at the lower end of the rod pusher clamps the ase of the screw, the upper U-shaped sticks to the upper end of the rod, and then press the handle to push the rod.

#### • Method 2:

The rod bender is inserted into the screw groove used to bend the rod, meanwhile, the rod pressed is realized.

#### • Method 3:

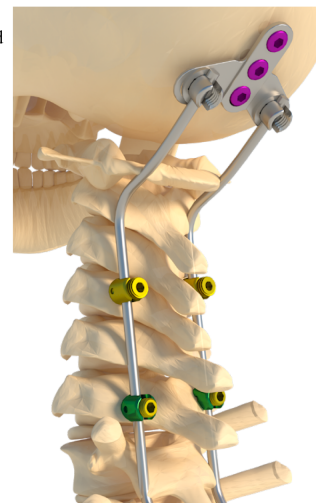
Hold the rod with the bottom groove of the rod pusher, clamp the screw tightly with the screwdriver, and then clamp the screwdriver to the middle cross beam of the rod pusher to form a linkage between the two. Turn the wrench of the rod pusher to press the rod.



## Surgical procedure

### 【Step 9】 Cervical screws pretension

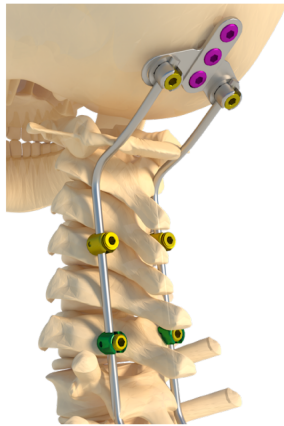
- Screw the plug into the U-shaped groove of the screw with a rovisional wrench, and preliminarily lock it.



## Surgical procedure

### 【Step 10】 Implant occipital screws

- Insert the selected occipital screw into the occipital hole with a screwdriver and cardan screwdriver. Pay attention to locking after all screws are inserted.



## Surgical procedure

### 【Step 11】 Final locking

- Lock all occipital screws and cervical screws from top to bottom, and install the transverse connector according to the actual situation. In this step, it is recommended to select limited torque wrench(3N/M) and anti torque wrench..



## Surgical procedure

### 【 Step 14 】

#### Graft for fusion

- Implant bone grafts or suitable fusion materials.

## Product information

### ● 【Fix Monoaxial Prdicle Screw(Self-tapping)】



		Length (mm)							
		16	18	20	22	24	26	28	30
Diameter (mm)	3.5	*	*	*	*	*	*	*	*
	4.0	*	*	*	*	*	*	*	*
		32	34	36	38	40	42	46	50
Diameter (mm)	4.0	*	*	*	*	*	*	*	*

### ● 【Fix Polyaxial Prdicle Screw(Self-tapping)】



		Length (mm)							
		10	12	14	16	18	20	22	
Diameter (mm)	3.5	*	*	*	*	*	*	*	
	4.0	*	*	*	*	*	*	*	
		24	26	28	30	32	34	36	
Diameter (mm)	4.0	*	*	*	*	*	*	*	
		38	40	42	46	50			
Diameter (mm)	4.0	*	*	*	*	*			

### ● 【Occipital Screw】



		Length (mm)					
		8	10	12	14	16	18
Diameter (mm)	3.5	*	*	*	*	*	*
	Color	light green	dark red	blue	golden	light blue	light green

### ● 【Occipital Screw】



		Length (mm)			
		8	10	12	
Diameter (mm)	4.5	*	*	*	
	Color	light green	dark red	blue	

## Product information

### ● 【Screw plug】



Specification	Code	Colour	Remark
Φ7	1420601035	Bronze	六方 SW3.0

### ● 【 Shifter 】



Specification	Code	Colour
Φ3.5×20	1416635029	light blue/blue

### ● 【Laminar hook】



Specification	Code	Remark
Φ3.5 Left	1415735011	light green 六方 SW3.0
Φ3.5 Right	1415835011	Dark red 六方 SW3.0
Φ3.5×16 Straight	1415635016	Golden 六方 SW3.0
Φ3.5×19 Straight	1415635019	Blue 六方 SW3.0

### ● 【Occipital titanium plate】



Specification	Code	Colour	Remark
32 3 孔 Holes	11400012	32 3 孔 Holes	六方 SW3.0
36 3 孔 Holes	11400011	36 3 孔 Holes	六方 SW3.0

### ● 【 Transverse hook 】



Specification	Code	Remark
Φ3.5	1413021010	Light blue 六方 SW3.0

### ● 【Trapezoid connector】



Specification	Code	Remark
Φ5.0-Φ3.5	012408000	六方 SW2.5
Φ5.5-Φ3.5	012416000	六方 SW2.5
Φ6.0-Φ3.5	012417000	六方 SW2.5

## Product information

### ● 【Occipital-cervical connecting rod】



Specification	Code
5 孔 Holes	0502003240
4 孔 Holes	0502004240

### ● 【Connecting rod(Hex)】



Specification	Code	Specification	Code
Φ3.5×40	1410035040	Φ3.5×65	1410035065
Φ3.5×45	1410035045	Φ3.5×70	1410035070
Φ3.5×50	1410035050	Φ3.5×140	1410035140
Φ3.5×55	1410035055	Φ3.5×210	1410035210
Φ3.5×60	1410035060		

### ● 【Gradient connecting rod】



Specification	Code
Φ3.5×100 - Φ5.0×100	0527050100
Φ3.5×100 - Φ5.0×190	0527050190
Φ3.5×100 - Φ5.0×200	0527050200
Φ3.5×100 - Φ6.0×100	0527060100
Φ3.5×100 - Φ6.0×200	0527060200
Φ3.5×100 - Φ5.5×100	0527055100
Φ3.5×100 - Φ5.5×200	0527055200

### ● 【Connecting rod】



Specification	Code	Specification	Code
Φ3.5×40	1409035040	Φ3.5×65	1409035065
Φ3.5×45	1409035045	Φ3.5×70	1409035070
Φ3.5×50	1409035050	Φ3.5×140	1409035140
Φ3.5×55	1409035055	Φ3.5×210	1409035210
Φ3.5×60	1409035060		

### ● 【Connecting rod】



Specification	Code
Φ3.0×40	1411030040
Φ3.0×45	1411030045
Φ3.0×50	1411030050
Φ3.0×55	1411030055

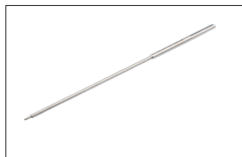
### ● 【Titanium rod (bend)】



Specification	Code
Φ3.5×130	0508035130

## Instrument information

### Special instrument



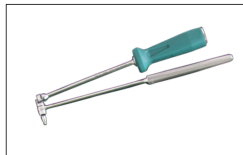
● 107-400  
Posterior cervical open drill



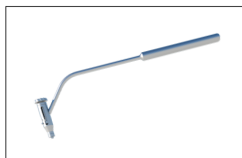
● 107-291  
Plate holder



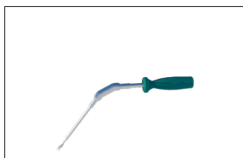
● 107-068  
Screwdriver



● 107-370  
Cardan screwdriver



● 107-332  
Drill guide (Φ3)



● 107-343  
Cardan drill



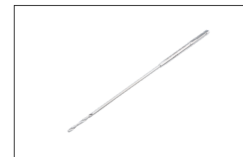
● 107-312  
Tap (Φ4.5)

## Instrument information

### Special instrument for connecting rod



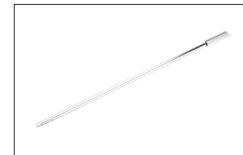
● 107-033  
Drill guide (Φ2.5)



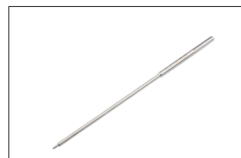
● 107-095  
Drill (Φ2.5)



● 107-067  
Screwdriver (self-holding, hex 2.5)



● 107-274  
Tap (Φ3)



● 107-148  
Awl



● 107-291  
Plate holder



● 107-068  
Screwdriver (self-holding, hex 3)



● 107-332  
Drill guide (Φ3)

## Instrument information

### General instrument



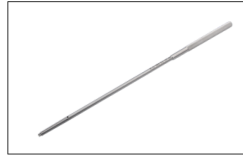
● 107-042  
3N.M torque wrench



● 107-051  
Counter-torque wrench



● 107-390  
Polyaxial screw hex-wrench



● 107-080  
Provisional wrench



● 107-101  
Posterior cervical rod holder



● 107-157  
Screw tap



● 107-360  
Posterior cervical open drill



● 107-156  
Expanding awl

## Instrument information



● 107-170  
Depth gauge



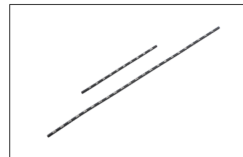
● 107-181  
Compressor



● 107-191  
Distractor



● 107-202  
Rod breaker



● 107-210/211  
Template



● 107-221  
Probe



● 107-240/241  
Positioning pin(pillar/bulb)



● 113-160  
Pin box

## Instrument information



● 107-262  
Screw holder



● 107-023  
Plate bender clamp



● 107-280  
Rod rotation clamp



● 107-166  
Rod pusher



● 107-231  
General handle

## Instrument information