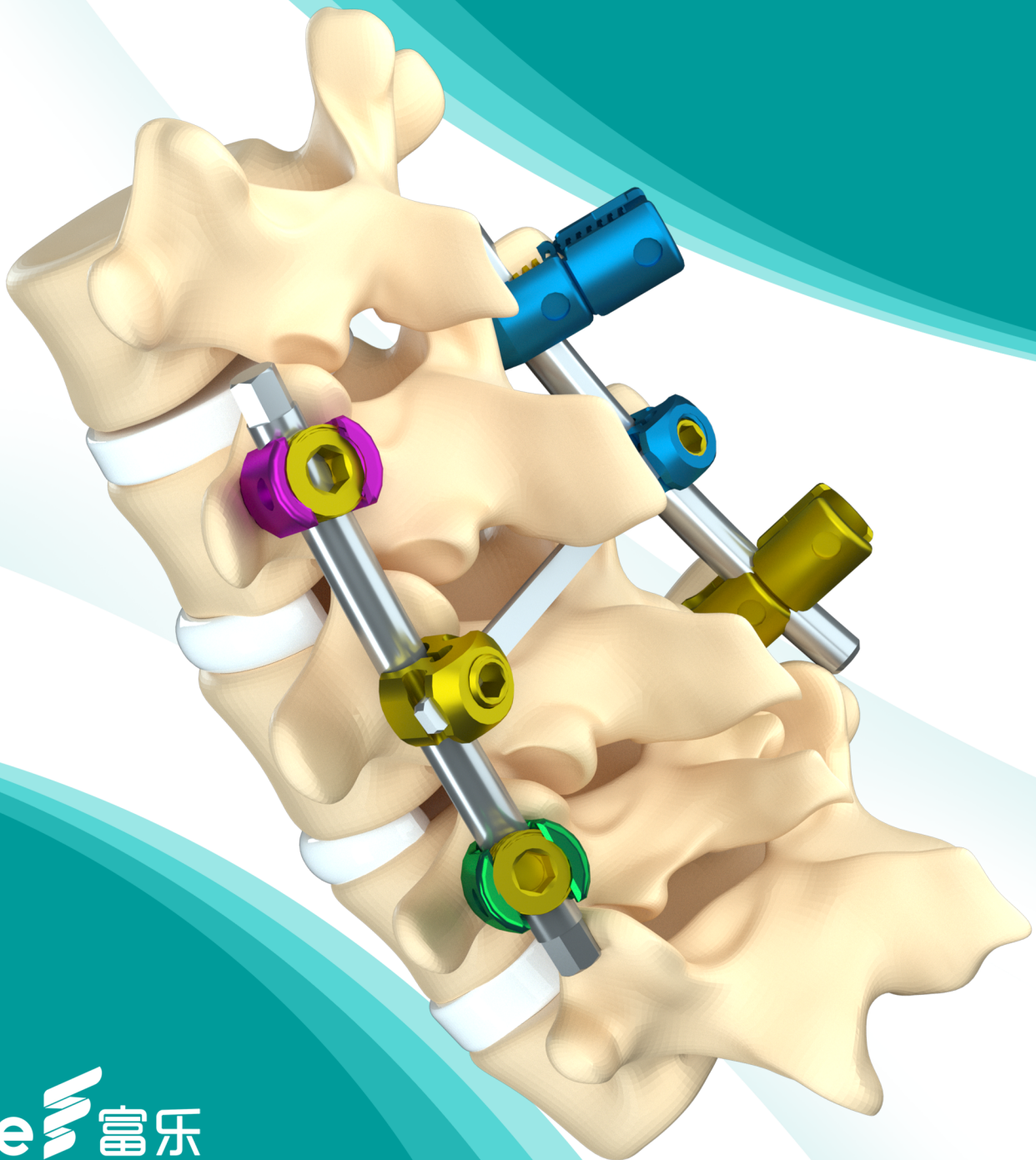


Cox II

Spinal Screw-Rod System

Surgical Technique



Why Choose FULE ? OUR ADVANTAGE

- TOP Two Spine Implants Manufacturer In China, providing Spine implants and instruments with good quality and service.
- We are Focusing On Orthopaedics more than 27 years, our products has been widely used by thousands of large and medium-sized hospitals.
- We have Excellent Distribution Channel and perfect after-sales service in Chinese main cities.
- We Offer OEM&ODM Service, we have our own professional designers to meet any of your requirements.



Beijing Fule Science & Technology Development Co., Ltd

Tel: 010-60999866/32/75/17 Email: YXSC@fulekeji.com

Post Code: 101204 Fax: 010-60999863/8741

Sale hot lines: 010-60999861/2

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



Shanghai International Holding Corp. GmbH(Europe)

Tel : +49-40-2513175//+49 163 6233205

Fax : +49-40-255726 E-mail : shholding@hotmail.com

Address: Eiffestrasse 80, 20537, Hamburg, Germany

CONCEPT

Product-Specific Advantages.....01

Indications for Use.....03

Surgical Technique.....04

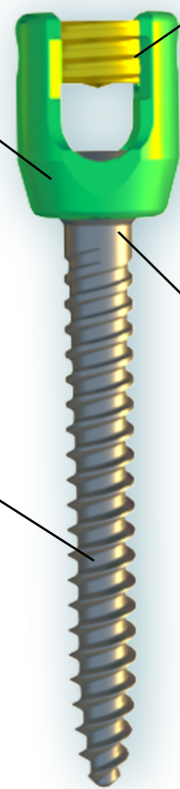
Implants Specification.....14

Surgical Instruments.....15

Product-Specific Advantages

Smaller connector volume, reduce the occupation for human tissue and irritability; The space of polyaxial screw in connecting rod is reduced, and the space of transverse connector and connecting rod is increased. Reduce the connector on the spinous process, transverse process interference, improve the flexibility of polyaxial screw, reduce the difficulty of surgery.

Bullet tip can make the implantation more easier; The double thread make implantation speed more faster; Enhance the pedicle screw strength, with better pull-out resistance and bending resistance.



Barb thread design, minimize the expansion of screw connector, to prevent screw plug pull out, avoid thread wrong buckle; Deepened screw thread design.

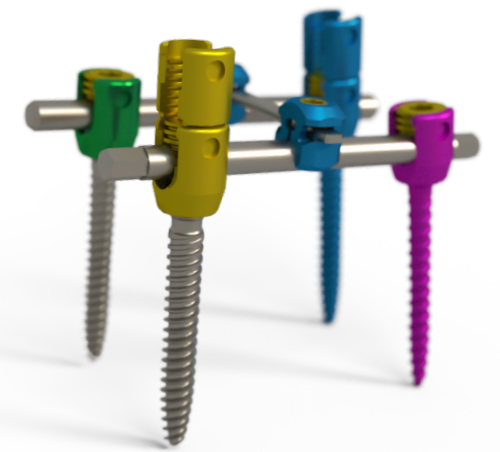
Optimize the polyaxial screw structure, the maximum assembly specification is ϕ 7.5. The pedicle screw structure has higher anti-spin ability (8N·m), and the ball head of thread part is not easy to come out; Press block release strength is up to 1600N, prevent press block release out.

CoCr rods in 5.5mm and 6.0mm provide confidence in correction stabilization.



Product-Specific Advantages

The COX II spinal screw rod system was designed with the changing healthcare environment, with the goal of developing an implant-based system that supports the efficiency and value of procedures while benefiting patients. At present, the COX II system has achieved optimization of surgical process, improved therapeutic efficacy, simple operation tools, and improved surgical safety, and provide a variety of specifications and models of products, suitable for the needs of various patients.



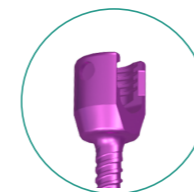
● Color-Coding Reference
NOTE: Color-coding available in titanium only.



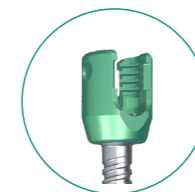
● 4.0mm



● 4.5mm



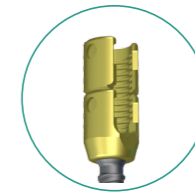
● 5.0mm



● 5.5mm



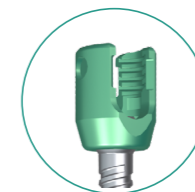
● 6.0mm



● 6.5mm



● 7.0mm



● 7.5mm

Indications for Use

● **【Attention and Suggestive Description】**

Please read the instruction before use carefully; Doctors should make clear the detailed notes to Patients in preoperative; If found have scratched the surface, broken, bent, crack phenomenon, the product is no longer available when delivered product;

Implants and instruments provided by our company are non sterilization, but the surgical instruments must be sterilized by high-pressure steam sterilization process before using.

● **【Indications】**

Various types of spinal fractures, including spinal burst fractures, compression fractures and fracture dislocation; short segment kyphosis orthopedic fixation; single segmental spinal instability or degenerative diseases.

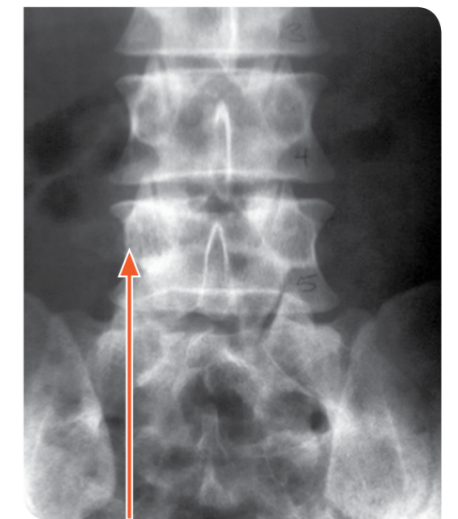
● **【Contraindications】**

Abnormal bone structure; nerve root canal anatomical abnormalities; serious neurological disorders; obesity; severe osteoporosis; metal allergy.

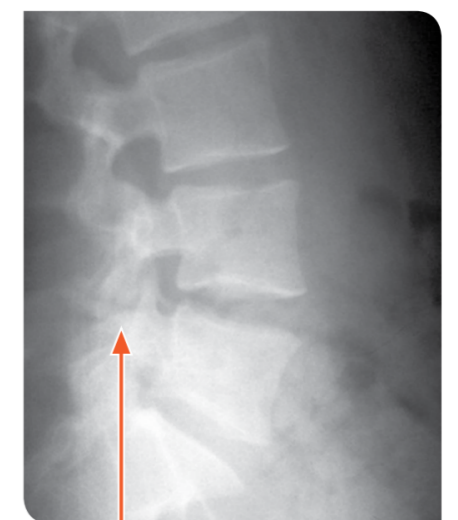
Surgical Technique

【Step 1】 INTRA-OP IMAGING

- Prior to preparing the pedicles for screw insertion, determine the Sagittal and Coronal orientation of the pedicles for the vertebrae to be instrumented.
- Identify the appropriate anatomical landmarks to create the entry points and pilot holes for screw insertion (Figures 1a and 1b).



Figures 1a

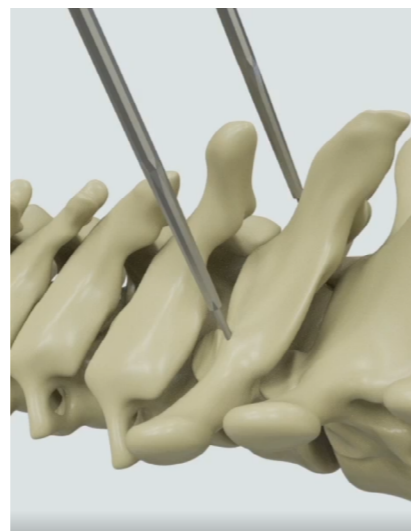


Figures 1b

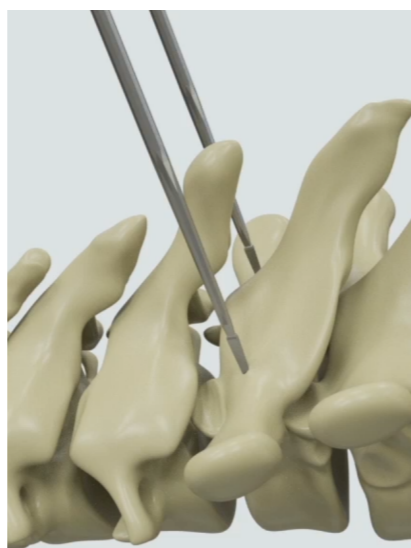
Surgical technique

[Step 2] PEDICLE PREPARATION

- Create a pilot hole in the pedicle at the junction of the transverse process and the superior articular process using the Awl (113-470)(Figures 2a) .
- Next, use a pedicle probe (113-022) to complete the cannulation of the pedicle (Figures 2b).
- Following preparation of the pedicle, a Feeler Probe (101-022) can be used to measure the depth.



Figures 2a

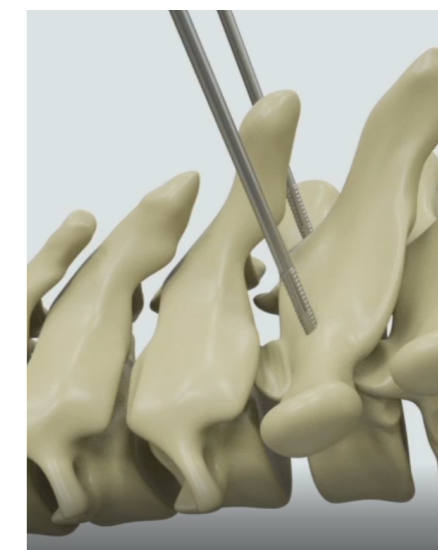


Figures 2b

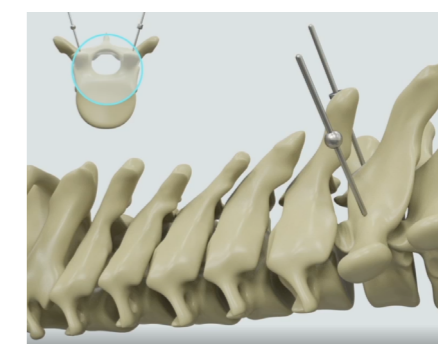
Surgical technique

[Step 2] PEDICLE PREPARATION

- The COXII Polyaxial Screws have self-tapping cutting flutes to obviate the need for tapping should the surgeon so choose. Therefore, pedicle screws may be inserted immediately following the preparation and verification of pedicle wall integrity.
- However, in cases of dense, sclerotic, or osteoporotic bone, tapping is recommended.
- Select the appropriate diameter tap (113-035), insert it into the pedicle and stop at the desired depth(Figures 2c).
- Following final preparation of the pedicle, pin (102-141/142) can be used to follow the tapped threads through the cancellous bone to confirm the position(Figures 2d).



Figures 2c

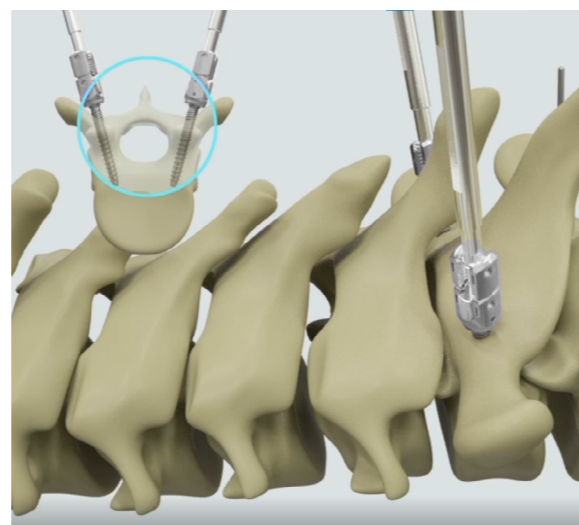


Figures 2d

Surgical technique

【Step 3】 SCREWDRIVER AND SCREW ASSEMBLY

- Assemble the Ratchet handle and the appropriate length pedicle screw onto the Locking Polyaxial Screwdriver.
- Connect the Ratchet Handle(113-133) onto the proximal end of the screwdriver and ensure the 1/4" square drive of the shaft is fully engaged with the handle.
- Once the screwdriver and screw assembly is complete, insert the screw into the pedicle(Figures 3a). Set the Axial Ratcheting Handle in the forward position and ratchet clockwise until the screw has reached the desired depth.

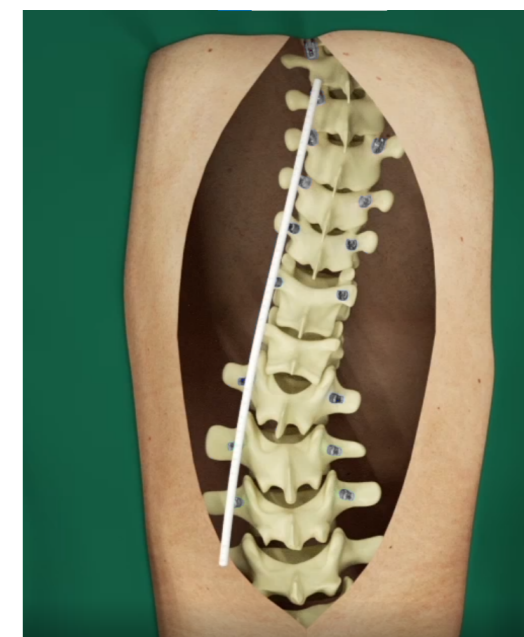


Figures 3a

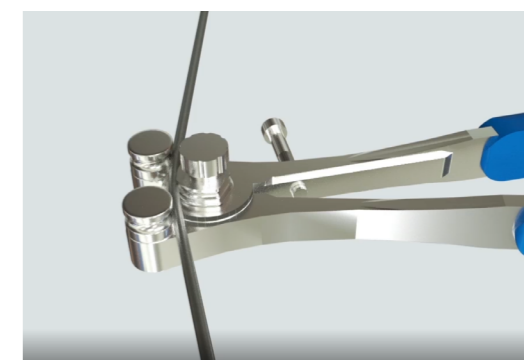
Surgical technique

【Step 4】 ROD MEASUREMENT & CONTOURING

- With the screws in place, the Rod Template(101-132) can be used to determine the appropriate rod contour and length(Figures 4a).
- If required, a Rod Cutter and Rod Bender(113-251) may be used to achieve the desired rod length and contour.(Figures 4b).



Figures 4a

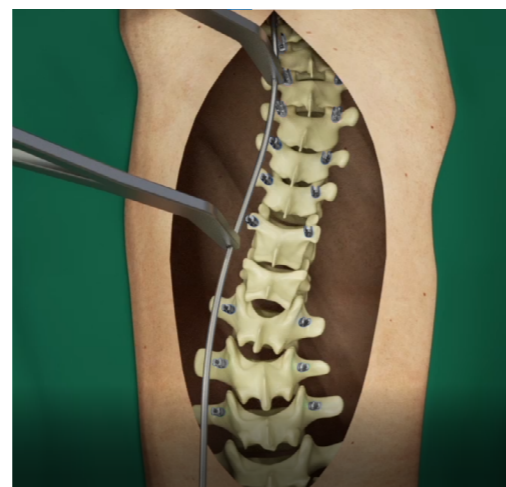


Figures 4b

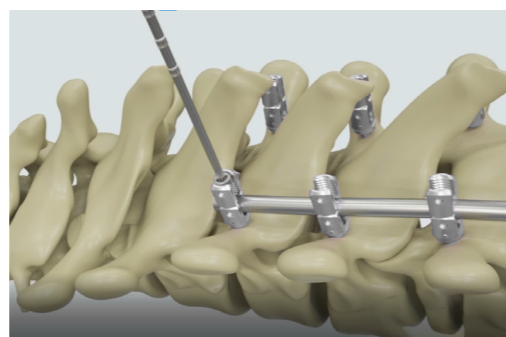
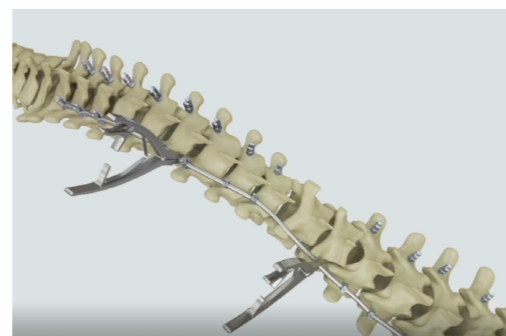
Surgical technique

【Step 5】 ROD INSERTION

- Place the rod using the rod holder (113-210) (Figures 5a).
- Use Rod Gripper(101-123), Rod Pusher(113-260) and Screw holder (113-270) to reset vertebral, after adjustment, tighten all plugs(Figures 5b and 5c).



Figures 5a

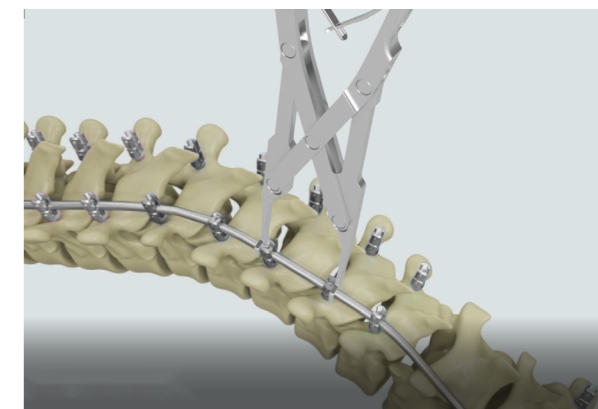


Figures 5b and 5c

Surgical technique

【Step 6】 PARALLEL COMPRESSION

- Compression can be performed at any instrumented level to restore sagittal alignment. To begin, tighten the set screw on one side of the motion segment and leave the set screw loose in the adjacent segment to be compressed.
- Place the Parallel Compressor (113-240) outside of the screw heads and over the rod. Squeeze the handles until adequate compression is attained(Figures 6a).
- Finally, use the Final locking screwdriver(113-500) to tighten the set screw and maintain compression

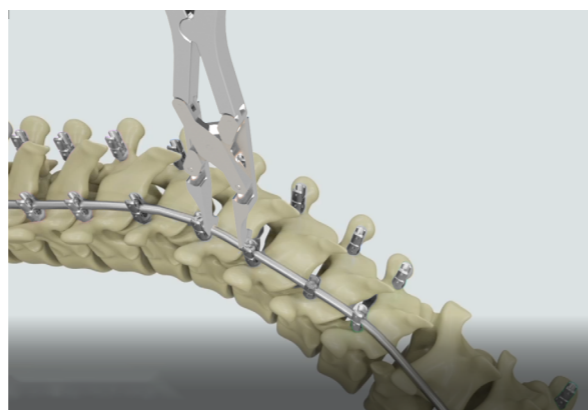


Figures 6a

Surgical technique

【Step 7】 PARALLEL DISTRACTION

- To begin, tighten the set screw on one side of the motion segment and leave the adjacent set screw loose. Place the tips of the Parallel Distractor(113-230) over the rod and between the implants, and then squeeze the handles to distract.
- When adequate distraction is attained, use the Final locking screwdriver(113-500) to tighten the set screw and maintain distraction (Figures 7a).

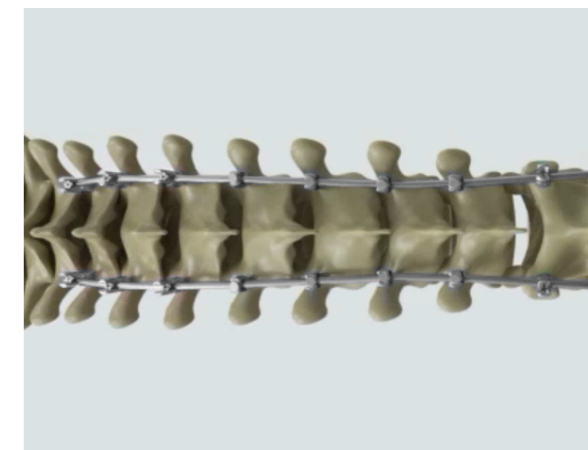


Figures 7a

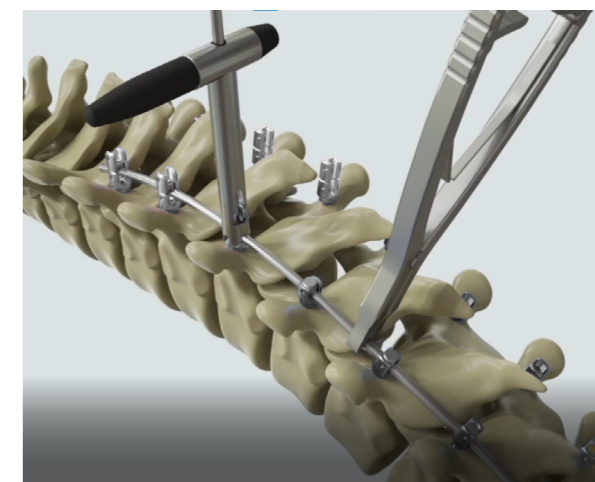
Surgical technique

【Step 8】 FINAL TIGHTENING

- Final tightening of the construct should be performed when all screws and rods are in their final position(Figures 8a).
- Connect the Counter Torque Handle(113-490) with the Final locking screwdriver(113-500) to tighten the plugs.
- Alternatively,Insert the Limited Torque Handle(113-421) assembly through the cannula of the Anti-Torque and engage the tip of the torque driver into the set screw(Figures 8b).
- Slide the Anti-Torque down until the instrument is fully seated over the rod and implant. Turn the T-Handle clockwise to tighten. Final tightening is achieved when the T-Handle audibly clicks .



Figures 8a

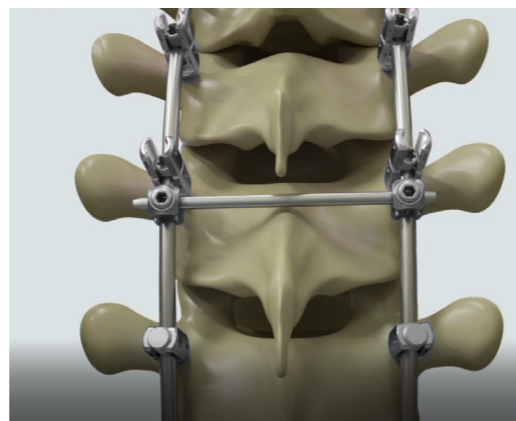


Figures 8b

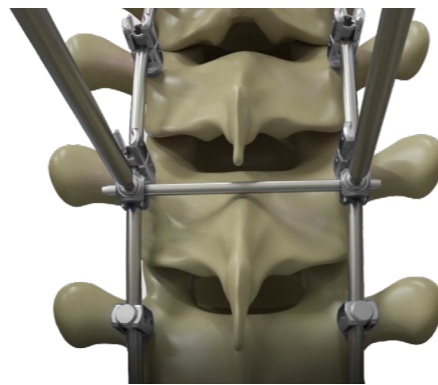
Surgical technique

[Step 9] TRANSVERSE CONNECT

- The COXII Variable Transverse Connector can be used to increase the torsional stability of a construct. Transverse Connector should be placed at each end of longer constructs to increase construct rigidity.
- Select the appropriate connector, use the connector holder(113-220) to engage a lateral set screw.
- Once precise contact has been achieved between the connector and the rods, the holder(113-220) can be used to provisionally tighten the connector to the rods(Figures 9a).
- To final tighten the transverse connector, use the screwdriver(113-081) to set the screws(Figures 9b).



Figures 9a



Figures 9b

Implants Specification

● [COX II Polyaxial Pedicle Screw]



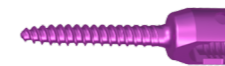
		Screw Length(mm)						
		25	30	35	40	45	50	55
Screw Diameter(mm)	4.0	*	*					
	4.5		*	*				
	5.0		*	*	*			
	5.5			*	*	*		
	6.0			*	*	*	*	
	6.5			*	*	*	*	
	7.0			*	*	*	*	*
	7.5			*	*	*	*	*

● [COX II Polyaxial Reduction Pedicle Screw]



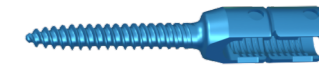
		Screw Length(mm)						
		25	30	35	40	45	50	55
Screw Diameter(mm)	4.0	*	*					
	4.5		*	*				
	5.0		*	*	*			
	5.5			*	*	*		
	6.0			*	*	*	*	
	6.5			*	*	*	*	
	7.0			*	*	*	*	*
	7.5			*	*	*	*	*

● [COX II Monoaxial Pedicle Screw]



		Screw Length(mm)						
		25	30	35	40	45	50	55
Screw Diameter(mm)	4.0	*	*					
	4.5		*	*				
	5.0		*	*	*			
	5.5			*	*	*		
	6.0			*	*	*	*	
	6.5			*	*	*	*	
	7.0			*	*	*	*	*
	7.5			*	*	*	*	*

● [COX II Monoaxial Reduction Pedicle Screw]



		Screw Length(mm)						
		25	30	35	40	45	50	55
Screw Diameter(mm)	4.0	*	*					
	4.5		*	*				
	5.0		*	*	*			
	5.5			*	*	*		
	6.0			*	*	*	*	
	6.5			*	*	*	*	
	7.0			*	*	*	*	*
	7.5			*	*	*	*	*

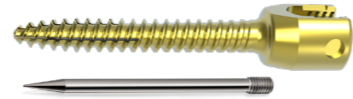
Implants Specification

● 【 COX II Polyaxial Reduction Pedicle Screw (Uniplanar)】



		Screw Length(mm)					
		25	30	35	40	45	50
Screw Diameter (mm)	4.0	*	*				
	4.5		*	*			
	5.0		*	*	*		
	5.5			*	*	*	
	6.0			*	*	*	*
	6.5			*	*	*	*

● 【 COX II Expandable Monoaxial Pedicle Screw】



		Screw Length(mm)			
		35	40	45	50
Screw Diameter (mm)	6.0	*	*	*	*
	6.5	*	*	*	*
	7.0	*	*	*	*

● 【 COX II Expandable Monoaxial Reduction Pedicle Screw】



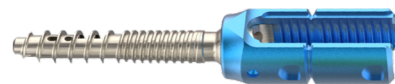
		Screw Length(mm)			
		35	40	45	50
Screw Diameter (mm)	6.0	*	*	*	*
	6.5	*	*	*	*
	7.0	*	*	*	*

● 【 COX II Bone Cement Monoaxial Reduction Pedicle Screw】



		Screw Length(mm)			
		35	40	45	50
Screw Diameter (mm)	5.5	*	*	*	
	6.0		*	*	*
	6.5		*	*	*

● 【 COX II Bone Cement Polyaxial Reduction Pedicle Screw】



		Screw Length(mm)			
		35	40	45	50
Screw Diameter (mm)	5.5	*	*	*	
	6.0		*	*	*
	6.5		*	*	*

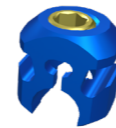
● 【 COX II Polyaxial Iliac Screw】



		Screw Length(mm)				
		70	75	80	85	90
Screw Diameter (mm)	7.5	*	*	*	*	*
	8.0		*	*	*	*
	8.5		*	*	*	*

Implants Specification

● 【 X Connector】



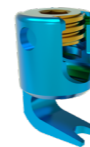
Description	
	Φ6.0

● 【 COX II Expandable Monoaxial Pedicle Screw】



Description	
	Φ10

● 【 COX II Pedicle Hook】



		Screw Length(mm)		
		6.5	7.0	8.0
Screw Diameter (mm)	6.0	*	*	*
	6.5			

● 【 COX II Laminar Hook】



		Screw Length(mm)		
		6.5	7.0	8.0
Screw Diameter (mm)	6.0	*	*	*
	6.5			

● 【 Rod for X Connector】



		Screw Length(mm)								
		40	45	50	55	60	65	70	75	80
Screw Diameter (mm)	4.0	*	*	*	*	*	*	*	*	*
	6.0									

● 【 Connecting Rod (Hex)】



		Screw Length(mm)							
		45	50	55	60	65	70	75	80
Screw Diameter (mm)	6.0	*	*	*	*	*	*	*	*
		*	*	*	*	*	*	*	*
		*	*	*	*	*	*	*	*
		*	*	*	*	*	*	*	*

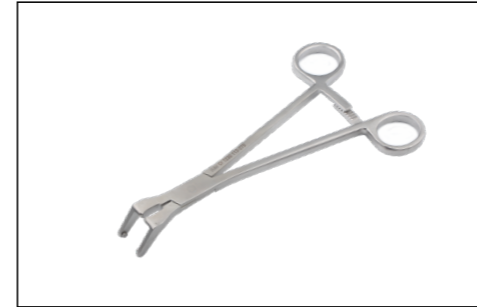
Implants Specification

● 【Connecting Rod】

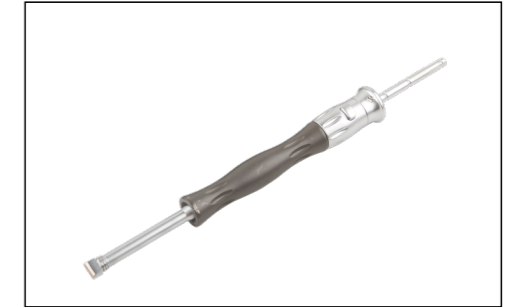


		Screw Length(mm)							
		40	45	50	55	60	65	70	
Screw Diameter (mm)	6.0	*	*	*	*	*	*	*	
		75	80	85	90	95	100	105	
		*	*	*	*	*	*	*	
		110	115	120	130	140	150	160	
		*	*	*	*	*	*	*	
		170	180	190	200	210	220	230	
		*	*	*	*	*	*	*	
		240	250	260	270	280	290	300	
		*	*	*	*	*	*	*	
		310	320	330	340	350	360	370	
		*	*	*	*	*	*	*	
		380	390	400	410	420	430	440	
		*	*	*	*	*	*	*	
		450	460	470	480	490	500		
*	*	*	*	*	*				

Surgical Instruments



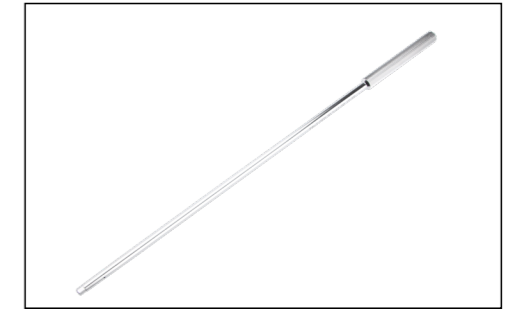
● 113-270
Screw Holder



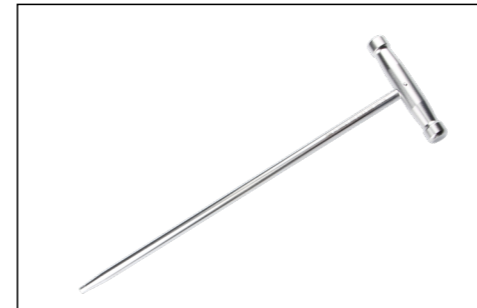
● 1010002
Monoaxial Pedicle Screwdriver



● 1010003
Polyaxial Pedicle Screwdriver



● 1010025
Nut Holder



● 102-216
T Type Nutdriver



● 102-131
Rod Gripper for Connecting Rod



● 1390007
Rod Persuader (Frog Type)



● 102-371
Extender for Rod Persuader (Frog Type)

Surgical Instruments



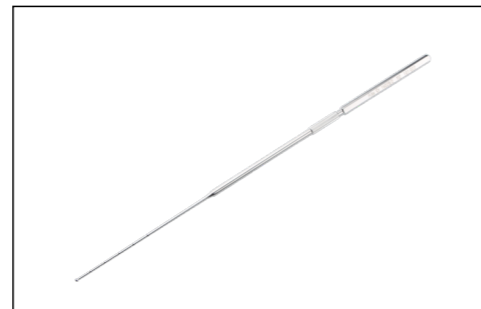
● 1390006
Counter Torque



● 1010014
Awl



● 1010016
Feeler Probe



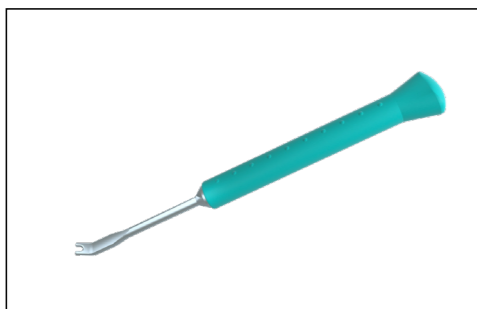
● 101-024
Probe



● 102-171
Depth Gauge



● 102-140
Pin Holder

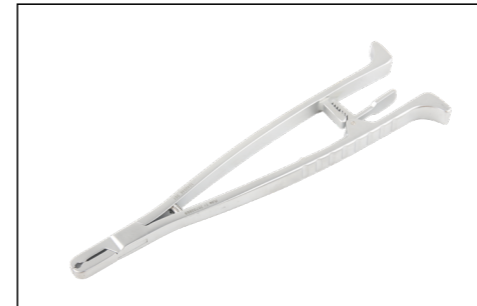


● 101-042
Rod Persuader

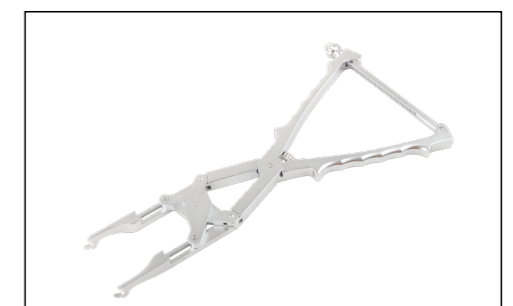


● 1010026
Rod Bender

Surgical Instruments



● 1040020
Rod Holder



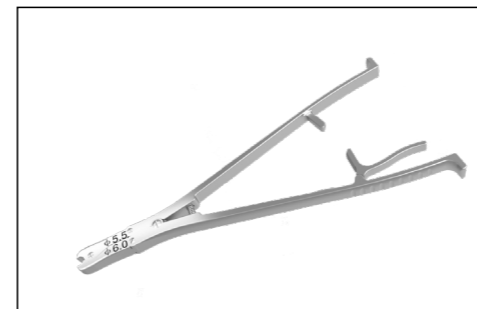
● 113-230
Parallel Distractor



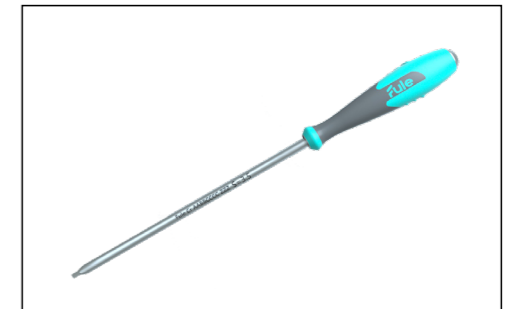
● 113-240
Parallel Compressor



● 1390002
Tap



● 101-123
Rod Gripper for Rotation



● 101-501
Hex Screwdriver



● 101-247
Ratchet Handle

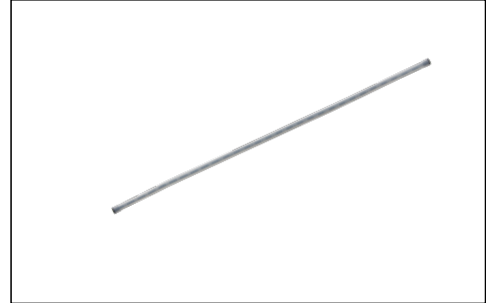


● 102-204
T Handle

Surgical Instruments



● 102-205
Straight Handle



● 101-132
Template



● 110-101
Break-off for Reduction Screw



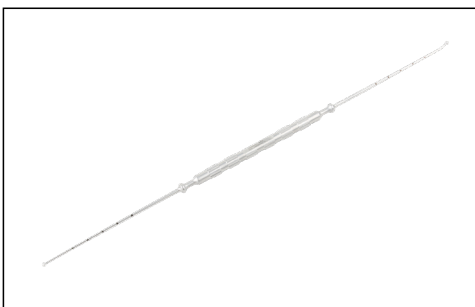
● 113-220
Hook Holder



● 102-141
Pin



● 102-142
Pin



● 113-330
Probe