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Spinal Pedicle Screw System (5.5mm System)

Instructions for Use



Material: TC4

Thoracolumbar fractures and lumbar
degenerative diseases.

Contents

01	Preface and Indications
03	Surgical Procedure
10	Product Informatin
17	Instrument Infommation

Preface and Indications

Preface

The Spinal Pedicle Screw System (5.5 mm System) is an implant system designed for posterior spinal internal fixation, consisting of pedicle screws, connecting rods, and related connection components. By establishing a stable spinal fixation construct, this system provides reliable biomechanical support for stabilization, deformity correction, and assisted fusion treatment in patients with spinal trauma, degenerative diseases, deformities, tumors, infections, and other related conditions.

This surgical technique manual is intended to provide healthcare professionals with relevant information regarding the product components, indications, contraindications, surgical procedures, instrument usage methods, precautions, and postoperative management of the Spinal Pedicle Screw System (5.5 mm System), guiding surgeons in the standardized and safe application of this system.

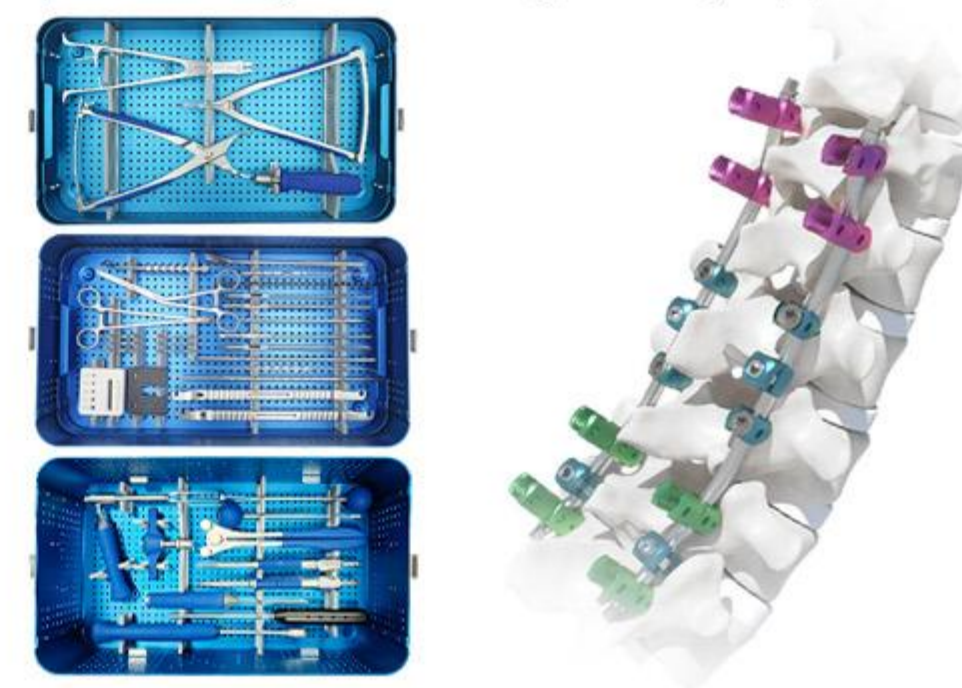
This system is designed to achieve spinal segment fixation and biomechanical reconstruction through the stable connection between pedicle screws and connecting rods. During surgery, appropriate implant specifications should be selected according to the patient's anatomical characteristics, pathological conditions, fixation range, and correction requirements. Strict compliance with the procedures specified in this manual is essential to ensure optimal system performance and patient safety.

Indications

This system is indicated for posterior internal fixation of the thoracic, thoracolumbar, and lumbar spinal segments. It is intended for patients requiring spinal stabilization, deformity correction, or assisted fusion treatment due to spinal instability caused by trauma, degenerative diseases, tumors, infections, or spinal deformities.

- Thoracolumbar fractures and associated spinal instability;
- Lumbar degenerative diseases, including lumbar disc herniation, lumbar spinal stenosis, degenerative lumbar spondylolisthesis, and discogenic low back pain;
- Thoracolumbar tumors and tuberculosis infections causing vertebral destruction, spinal instability, or requiring reconstructive fixation;
- Thoracolumbar deformities, including scoliosis and other conditions requiring deformity correction and stabilization.

This system forms a stable internal fixation construct through the use of pedicle screws, connecting rods, and related components, providing restoration and maintenance of spinal stability while offering auxiliary support for bone fusion.



Surgical Procedure

1. Patient Positioning

Patients are typically positioned in the prone position for surgery. After completion of anesthesia, the patient is carefully transferred to the operating table and appropriate positioning supports are used to maintain body stability.



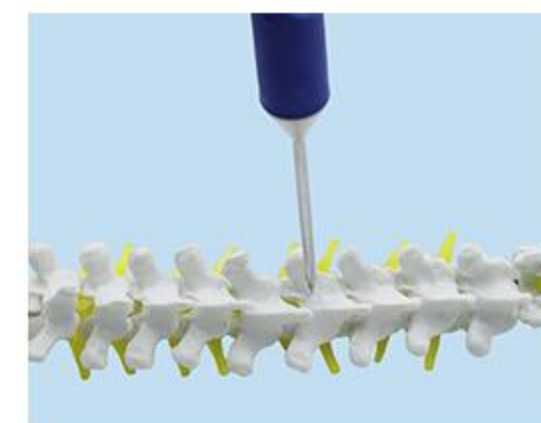
2. Rod Selection

Select the appropriate 5.5 mm connecting rod according to the patient's anatomical characteristics, the number of fixation levels, correction requirements, and preoperative imaging evaluation.

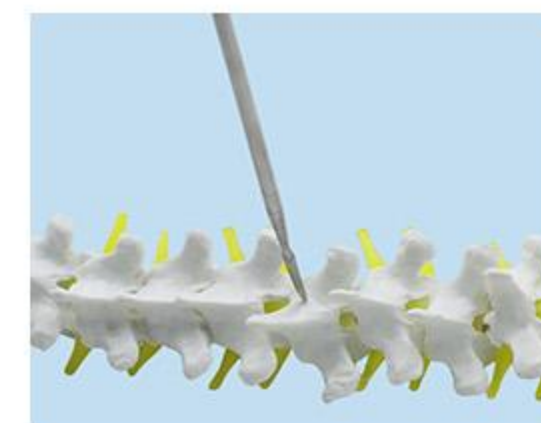


3. Pedicle Screw System Implantation Procedure

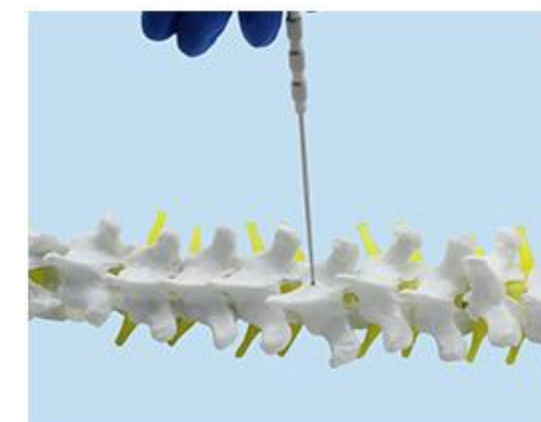
1. Use the awl to create a precise entry pathway for pedicle screw placement.



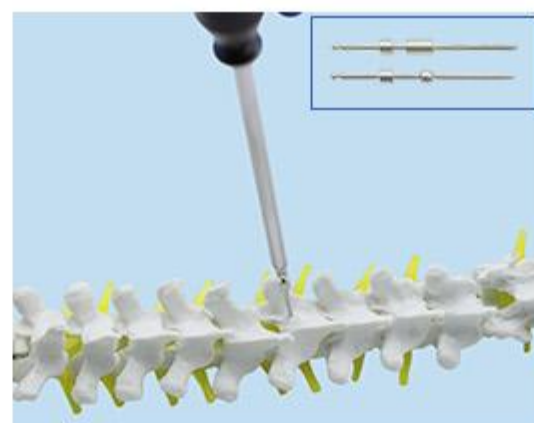
2. After establishing the entry pathway, use the dilator to enlarge the channel, ensuring smooth and accurate pedicle screw placement.



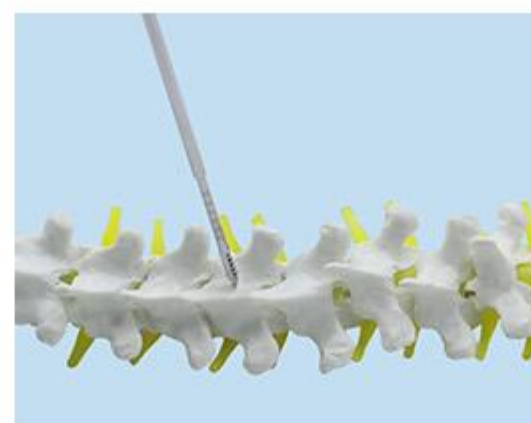
3. Rotate the probe for depth assessment to confirm the integrity of the pathway and ensure no cortical breach.



4. Use the marker pin for precise localization, and confirm the trajectory and intended pedicle screw placement position through CT imaging to ensure accurate positioning.



5. Based on preoperative bone density assessment, patients with higher bone density are recommended to undergo tapping with a ratchet handle and tap. For osteoporotic patients, tapping may be omitted according to clinical conditions.



6. Connect the screw inserter to the proximal thread of the pedicle screw head and tighten securely to ensure stable fixation without loosening or wobbling during the procedure.



7. Place the rod template between the two pedicle screws to measure the required length and select the appropriate 5.5 rod. Use the template rod for temporary contouring to confirm the spinal alignment and curvature.



8. Determine the required rod length according to the template rod measurement and select the appropriate titanium rod. Use the rod bender to contour



9. Use the rod holder forceps to securely grasp the rod and accurately position it into the screw head.



10. Use the pre-locking screwdriver to insert the set screw into the screw head for preliminary fixation.



11. Use the pre-tightening wrench to insert the set screw into the pedicle screw head, then perform preliminary tightening with the final locking screwdriver while maintaining sufficient space for subsequent distraction or compression adjustments.



12. According to the preoperative plan, use compression or distraction forceps to precisely adjust the fixed spinal segments, restore spinal alignment, and assist in relieving intervertebral disc compression.



13. For rod systems with a hexagonal feature, a rod rotation wrench can be used for controlled rod rotation and intraoperative adjustment.



14. Finally, use the screw tail breaker to remove the long-tail extensions, completing the final fixation procedure.



15. If additional construct stability is required, a transverse connector can be installed. Use the transverse connector holder forceps to securely grasp and accurately position the connector between the two rods, then tighten it with the transverse connector screwdriver for stable fixation.



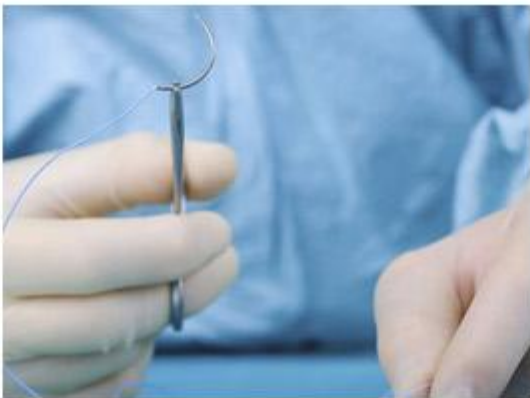
Product Informatin

Monoaxial Pedical Screw

16. Use the torque handle in combination with the counter torque wrench to perform final locking.



17. Complete distraction, compression, and necessary corrective adjustments according to the preoperative plan. Use the counter torque wrench, torque handle, and final locking screwdriver to perform final tightening of the set screws. After confirming construct stability, proceed with wound closure.



REF	Specification
R55ZDD4540	Φ4.5*40mm
R55ZDD4545	Φ4.5*45mm
R55ZDD5030	Φ5.0*30mm
R55ZDD5035	Φ5.0*35mm
R55ZDD5040	Φ5.0*40mm
R55ZDD5045	Φ5.0*45mm
R55ZDD5535	Φ5.5*35mm
R55ZDD5540	Φ5.5*40mm
R55ZDD5545	Φ5.5*45mm
R55ZDD5550	Φ5.5*50mm
R55ZDD6035	Φ6.0*35mm
R55ZDD6040	Φ6.0*40mm
R55ZDD6045	Φ6.0*45mm
R55ZDD6050	Φ6.0*50mm
R55ZDD6535	Φ6.5*35mm
R55ZDD6540	Φ6.5*40mm
R55ZDD6545	Φ6.5*45mm
R55ZDD6550	Φ6.5*50mm
R55ZDD7035	Φ7.0*35mm

REF	Specification
R55ZDD7040	Φ7.0*40mm
R55ZDD7045	Φ7.0*45mm
R55ZDD7050	Φ7.0*50mm

Monoaxial Reduction Screw



REF	Specification
R55ZDC5030	Φ5.0*30mm
R55ZDC5035	Φ5.0*35mm
R55ZDC5040	Φ5.0*40mm
R55ZDC5045	Φ5.0*45mm
R55ZDC5535	Φ5.5*35mm
R55ZDC5540	Φ5.5*40mm
R55ZDC5545	Φ5.5*45mm
R55ZDC5550	Φ5.5*50mm
R55ZDC6035	Φ6.0*35mm
R55ZDC6040	Φ6.0*40mm
R55ZDC6045	Φ6.0*45mm
R55ZDC6050	Φ6.0*50mm
R55ZDC6535	Φ6.5*35mm
R55ZDC6540	Φ6.5*40mm
R55ZDC6545	Φ6.5*45mm
R55ZDC6550	Φ6.5*50mm

REF	Specification
R55ZDC7035	Φ7.0*35mm
R55ZDC7040	Φ7.0*40mm
R55ZDC7045	Φ7.0*45mm
R55ZDC7050	Φ7.0*50mm

Polyaxial Pedical Screw



REF	Specification
R55ZWD4530	4.5*30mm
R55ZWD4535	4.5*35mm
R55ZWD4540	4.5*40mm
R55ZWD4545	4.5*45mm
R55ZWD5030	Φ5.0*30mm
R55ZWD5035	Φ5.0*35mm
R55ZWD5040	Φ5.0*40mm
R55ZWD5045	Φ5.0*45mm
R55ZWD5535	Φ5.5*35mm
R55ZWD5540	Φ5.5*40mm
R55ZWD5545	Φ5.5*45mm
R55ZWD5550	Φ5.5*50mm
R55ZWD6035	Φ6.0*35mm
R55ZWD6040	Φ6.0*40mm
R55ZWD6045	Φ6.0*45mm
R55ZWD6050	Φ6.0*50mm
R55ZWD6535	Φ6.5*35mm

REF	Specification
R55ZWD6040	Φ6.0*40mm
R55ZWD6045	Φ6.0*45mm
R55ZWD6050	Φ6.0*50mm
R55ZWD6535	Φ6.5*35mm
R55ZWD6540	Φ6.5*40mm
R55ZWD6545	Φ6.5*45mm
R55ZWD6550	Φ6.5*50mm
R55ZWD6555	Φ6.5*55mm
R55ZWD7035	Φ7.0*35mm
R55ZWD7040	Φ7.0*40mm
R55ZWD7045	Φ7.0*45mm
R55ZWD7050	Φ7.0*50mm

Polyaxial Reduction Screw



REF	Specification
R55ZWC5030	Φ5.0*30mm
R55ZWC5035	Φ5.0*35mm
R55ZWC5040	Φ5.0*40mm
R55ZWC5045	Φ5.0*45mm
R55ZWC5535	Φ5.5*35mm
R55ZWC5540	Φ5.5*40mm
R55ZWC5545	Φ5.5*45mm
R55ZWC5550	Φ5.5*50mm
R55ZWC6035	Φ6.0*35mm

REF	Specification
R55ZWC6040	Φ6.0*40mm
R55ZWC6045	Φ6.0*45mm
R55ZWC6050	Φ6.0*50mm
R55ZWC6535	Φ6.5*35mm
R55ZWC6540	Φ6.5*40mm
R55ZWC6545	Φ6.5*45mm
R55ZWC6550	Φ6.5*50mm
R55ZWC7035	Φ7.0*35mm
R55ZWC7040	Φ7.0*40mm
R55ZWC7045	Φ7.0*45mm
R55ZWC7050	Φ7.0*50mm

Crosslink



REF	Specification
RHL5560	60mm
RHL5570	70mm
RHL5580	80mm

Rod



REF	Specification
TB55100	Φ5.5*100mm
TB55150	Φ5.5*150mm
TB55200	Φ5.5*200mm
TB55250	Φ5.5*250mm
TB55300	Φ5.5*300mm
TB55350	Φ5.5*350mm
TB55400	Φ5.5*400mm

Gradient Titanium Rod



REF	Specification
TB35100JT55200	Φ3.5*100-Φ5.5*200mm

Domino Bolt

REF	Specification
DMN55G60	5.5/6.0mm

5.5 Iliac Pedicle Screw



REF	Specification
R55ZDG7565	Φ7.5*65mm
R55ZDG7570	Φ7.5*70mm
R55ZDG7575	Φ7.5*75mm
R55ZDG7580	Φ7.5*80mm
R55ZDG8065	Φ8.0*65mm
R55ZDG8070	Φ8.0*70mm
R55ZDG8075	Φ8.0*75mm
R55ZDG8080	Φ8.0*80mm

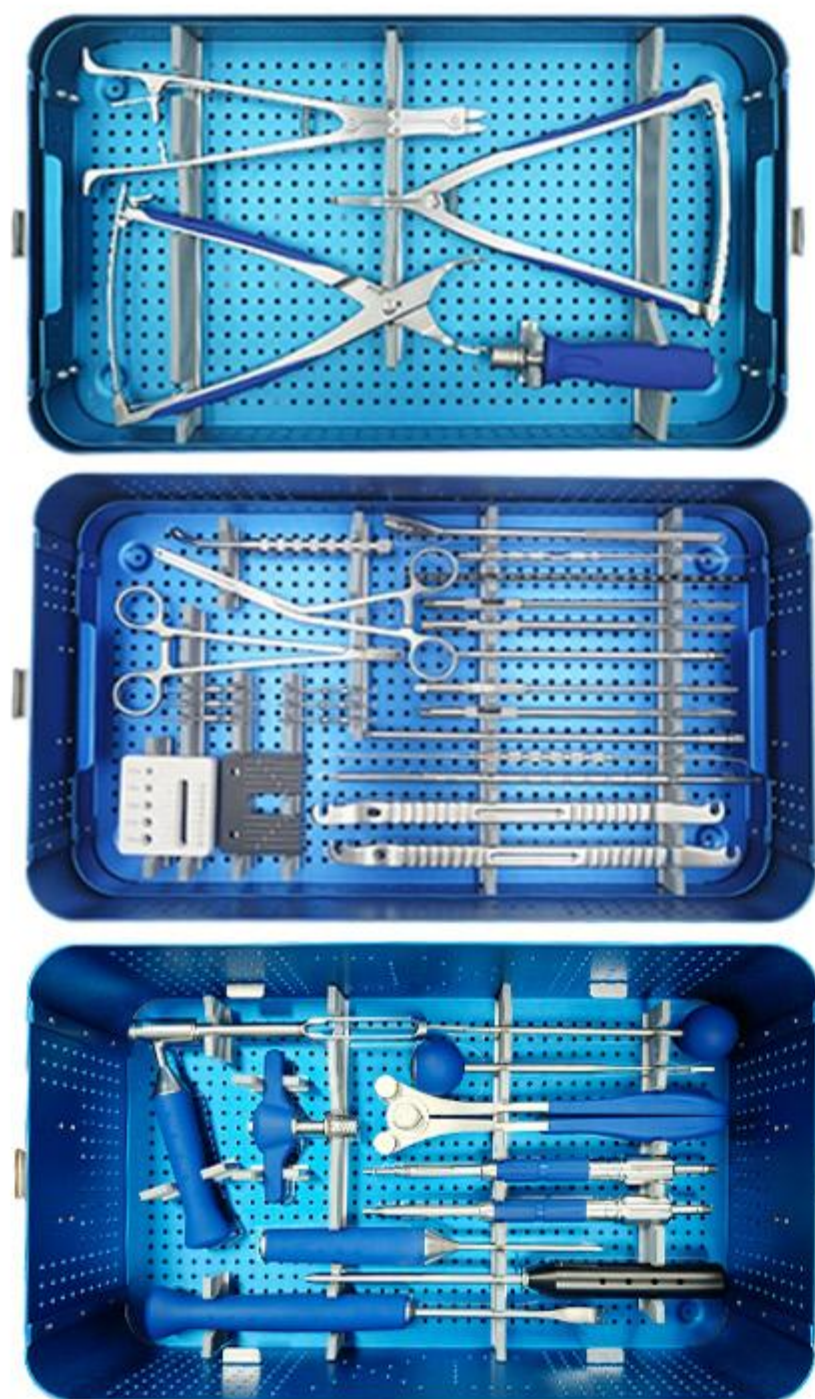
5.5 Iliac Pedicle Screw Shifter



REF	Specification
R55ZDGZ5530	5.5*30
R55ZDGZ5540	5.5*40
R55ZDGZ5550	5.5*50
R55ZDGZ5560	5.5*60

Instrument Infommation

5.5mm Spinal Pedicle Screw System Instrument Set



RQ55JNGD01

REF	Specification	Qty.
RQJSTZ	Double-Head Probe	1
RQJYTZ	Single-head Probe (stiff)	1
RQ5JSZ45	Tap 4.5	1
RQ5JSZ55	Tap 5.5	1
RQ5JSZ65	Tap 6.5	1
RQ5JSZ75	Tap 7.5	1
TYMB55200G	Mould Rod 200	1
RQ5JHSW35	Crosslink Screwdriver SW3.5	1
RQ5JDWZDQ	Screw Tab Breaker	1
RQ5JZHSW35	Self-retaining Crosslink Screwdriver SW3.5	1
RQ5JYJT27	Holding Screwdriver T27	1
RQ5JTWQL	In-situ Rod Bender (L)	1
RQ5JTWQR	In-situ Rod Bender (R)	1
RQJZKLQ32	3.2 Pedicle Probe	1
RQJWKLQ	Curved Pedicle Probe	1
RQ5JZSJT27	Tightening Screwdriver T27	1
RQJQXZ	Ball-type Fixation Pin	4
RQJZXZ	Pillar-type Fixation Pin	4
RQ5JHCLC	Crosslink Measurement	1
RQ5JLDCLC	Screw Measurement	1
RQ5JHCBQ	Crosslink Rod Holding Forceps	1
RQ5JYSQ	Compressor	1
RQ5JCKQ	Spreader	1
RQ5JZBQ	Rod Twister (double-joint) 5.5	1

REF	Specification	Qty.
RQ5JDKBS	Counter Sleeve	1
RQ5JTKSBSF	T-handle Quick Coupling Handle	1
RQ6JXBSW5	Rod Twist Wrench SW5.0	1
RQ5JKLZ	AWL	1
RQJWBQG	Rod Bender (silicone handle)	1
RQ5JCYBQ	C-type Rod Persuader	1
RQJXZQ	Fixation Pin Holder	1
RQ5JCBQ	Rod Holding Forceps	1
RQJZKSBSF	Straight Quick Coupling Handle (square connection)	1
RQ5JSDQW	Screwdriver for Polyaxial Screw	1
RQ5JSDQD	Screwdriver for Monoaxial Screw	1
RQ5JMJHL	Instrument Box	1

Optional

REF	Specification	Qty.
RQ5JCTT	Sleeve (5.5, long)	1
RQ5JWFQ	Frog Reduction Forceps	1
RQJ12NMSF	12N.m Torque Wrench	1
RQJJLSF	Ratchet Handle	1
RQ5JCWYBQ	Rod Pushing Forceps	1