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Spinal Pedicle Screw System (6.0mm System)

Instructions for Use



Material: TC4

Thoracolumbar fractures and lumbar
degenerative diseases.

Contents

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

Preface and Indications

Preface

The Spinal Pedicle Screw System (6.0 mm System) is an implant system designed for posterior spinal fixation and stabilization. Through the combined application of pedicle screws, connecting rods, and related components, it provides reliable biomechanical support for spinal reconstruction, deformity correction, and stabilization.

This system is intended for internal fixation treatment of the thoracolumbar spine and below, including the sacral spine, for conditions that meet the applicable indications.

This surgical technique manual is intended to provide healthcare professionals with relevant information regarding the components, indications, surgical procedures, and product specifications of the Spinal Pedicle Screw System (6.0 mm System), guiding the standardized and safe clinical use of this system.

Proper selection of implant specifications suitable for the patient's anatomical structure and treatment requirements, along with strict adherence to the procedures specified in this manual, is essential to ensure the safety, stability, and effectiveness of the system. During surgery, imaging evaluation and clinical judgment should be combined to ensure accurate implant positioning and reliable fixation.

Indications

This system is indicated for posterior internal fixation of the thoracic spine, thoracolumbar spine, lumbar spine, and sacral segments. It is applicable for the following clinical conditions:

- 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, tuberculosis, and other conditions causing structural damage or instability of the spine;
- Thoracolumbar deformities, including scoliosis and other conditions requiring deformity correction and stabilization.

This system is designed to establish a posterior spinal fixation construct through the use of pedicle screws, connecting rods, and related components, providing spinal stabilization, deformity correction, and assistance in spinal fusion procedures.



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

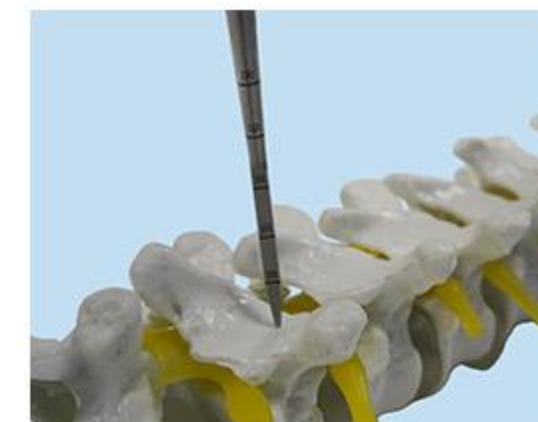


3. Pedicle Screw System Implantation Procedure

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. Perform rotational probing to assess the depth and confirm the integrity of the pedicle pathway without cortical wall breach.



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



5. Based on preoperative bone density assessment, patients with higher bone density are recommended to undergo pre-tapping using a ratchet handle with a tap to prepare the screw insertion pathway. For osteoporotic patients, tapping may be omitted according to intraoperative 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 6.0 rod. Use the template rod for temporary contouring to confirm the overall spinal curvature and correction profile.



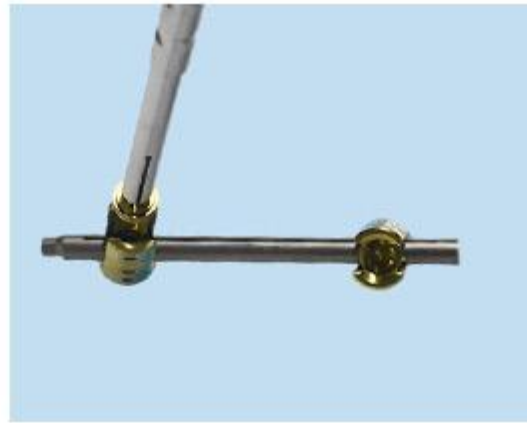
8. Use the rod bender to precisely contour the rod according to the patient's physiological spinal curvature, ensuring optimal anatomical alignment.



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 an appropriate gap 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.



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



15. Finally, use the rod/screw tail breaker to remove the long-tail screw extensions, completing the final screw preparation.



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



17. Complete distraction, compression, and necessary minor 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.



Product Informatin

Monoaxial Pedicle Screw

REF	Specification
R6ZDD4525	Φ4.5*25mm
R6ZDD4530	Φ4.5*30mm
R6ZDD4535	Φ4.5*35mm
R6ZDD4540	Φ4.5*40mm
R6ZDD4545	Φ4.5*45mm
R6ZDD4550	Φ4.5*50mm
R6ZDD4555	Φ4.5*55mm
R6ZDD5030	Φ5.0*30mm
R6ZDD5035	Φ5.0*35mm
R6ZDD5040	Φ5.0*40mm
R6ZDD5045	Φ5.0*45mm
R6ZDD5050	Φ5.0*50mm
R6ZDD5055	Φ5.0*55mm
R6ZDD5530	Φ5.5*30mm
R6ZDD5535	Φ5.5*35mm
R6ZDD5540	Φ5.5*40mm
R6ZDD5545	Φ5.5*45mm
R6ZDD5550	Φ5.5*50mm
R6ZDD5555	Φ5.5*55mm

REF	Specification
R6ZDD6030	Φ6.0*30mm
R6ZDD6035	Φ6.0*35mm
R6ZDD6040	Φ6.0*40mm
R6ZDD6045	Φ6.0*45mm
R6ZDD6050	Φ6.0*50mm
R6ZDD6055	Φ6.0*55mm
R6ZDD6530	Φ6.5*30mm
R6ZDD6535	Φ6.5*35mm
R6ZDD6540	Φ6.5*40mm
R6ZDD6545	Φ6.5*45mm
R6ZDD6550	Φ6.5*50mm
R6ZDD7035	Φ7.0*35mm
R6ZDD7040	Φ7.0*40mm
R6ZDD7045	Φ7.0*45mm
R6ZDD7050	Φ7.0*50mm
R6ZDD7055	Φ7.0*55mm

Monoaxial Reduction Screw

REF	Specification
R6ZDC5030	Φ5.0*30mm
R6ZDC5035	Φ5.0*35mm
R6ZDC5040	Φ5.0*40mm
R6ZDC5045	Φ5.0*45mm
R6ZDC5530	Φ5.5*30mm



REF	Specification
R6ZDC5535	Φ5.5*35mm
R6ZDC5540	Φ5.5*40mm
R6ZDC5545	Φ5.5*45mm
R6ZDC5550	Φ5.5*50mm
R6ZDC6035	Φ6.0*35mm
R6ZDC6040	Φ6.0*40mm
R6ZDC6045	Φ6.0*45mm
R6ZDC6050	Φ6.0*50mm
R6ZDC6035	Φ6.5*35mm
R6ZDC6540	Φ6.5*40mm
R6ZDC6545	Φ6.5*45mm
R6ZDC6550	Φ6.5*50mm
R6ZDC7035	Φ7.0*35mm
R6ZDC7040	Φ7.0*40mm
R6ZDC7045	Φ7.0*45mm
R6ZDC7050	Φ7.0*50mm

Polyaxial Pedical Screw

REF	Specification
R6ZWD4520	Φ4.5*20mm
R6ZWD4525	Φ4.5*25mm
R6ZWD4530	Φ4.5*30mm
R6ZWD4535	Φ4.5*35mm
R6ZWD4540	Φ4.5*40mm



REF	Specification
R6ZWD4545	Φ4.5*45mm
R6ZWD4550	Φ4.5*50mm
R6ZWD4555	Φ4.5*55mm
R6ZWD5030	Φ5.0*30mm
R6ZWD5035	Φ5.0*35mm
R6ZWD5040	Φ5.0*40mm
R6ZWD5045	Φ5.0*45mm
R6ZWD5050	Φ5.0*50mm
R6ZWD5055	Φ5.0*55mm
R6ZWD5530	Φ5.5*30mm
R6ZWD5535	Φ5.5*35mm
R6ZWD5540	Φ5.5*40mm
R6ZWD5545	Φ5.5*45mm
R6ZWD5550	Φ5.5*50mm
R6ZWD5555	Φ5.5*55mm
R6ZWD6035	Φ6.0*35mm
R6ZWD6040	Φ6.0*40mm
R6ZWD6045	Φ6.0*45mm
R6ZWD6050	Φ6.0*50mm
R6ZWD6055	Φ6.0*55mm
R6ZWD6530	Φ6.5*30mm
R6ZWD6535	Φ6.5*35mm
R6ZWD6540	Φ6.5*40mm
R6ZWD6545	Φ6.5*45mm

REF	Specification
R6ZWD6550	Φ6.5*50mm
R6ZWD7035	Φ7.0*35mm
R6ZWD7040	Φ7.0*40mm
R6ZWD7045	Φ7.0*45mm
R6ZWD7050	Φ7.0*50mm

Polyaxial Reduction Screw



REF	Specification
R6ZWC5030	Φ5.0*30mm
R6ZWC5035	Φ5.0*35mm
R6ZWC5040	Φ5.0*40mm
R6ZWC5530	Φ5.5*30mm
R6ZWC5535	Φ5.5*35mm
R6ZWC5540	Φ5.5*40mm
R6ZWC5545	Φ5.5*45mm
R6ZWC5550	Φ5.5*50mm
R6ZWC6035	Φ6.0*35mm
R6ZWC6040	Φ6.0*40mm
R6ZWC6045	Φ6.0*45mm
R6ZWC6050	Φ6.0*50mm
R6ZWC6535	Φ6.5*35mm
R6ZWC6540	Φ6.5*40mm
R6ZWC6545	Φ6.5*45mm

REF	Specification
R6ZWC6550	Φ6.5*50mm
R6ZWC7035	Φ7.0*35mm
R6ZWC7040	Φ7.0*40mm
R6ZWC7045	Φ7.0*45mm
R6ZWC7050	Φ7.0*50mm

Crosslink



REF	Specification
RHL6060	60mm
RHL6070	70mm
RHL6080	80mm

Gradient Titanium Rod



REF	Specification
TB35100JT60200	3.5*100-6.0*200mm

Rod



REF	Specification
TB60100	Φ6.0*100mm
TB60150	Φ6.0*150mm
TB60200	Φ6.0*200mm
TB60250	Φ6.0*250mm
TB60300	Φ6.0*300mm
TB60350	Φ6.0*350mm
TB60400	Φ6.0*400mm

Gradient Titanium Rod



REF	Specification
R6ZDG7565	Φ7.5*65mm
R6ZDG7570	Φ7.5*70mm
R6ZDG7575	Φ7.5*75mm
R6ZDG7580	Φ7.5*80mm
R6ZDG8065	Φ8.0*65mm
R6ZDG8070	Φ8.0*70mm
R6ZDG8075	Φ8.0*75mm
R6ZDG8080	Φ8.0*80mm

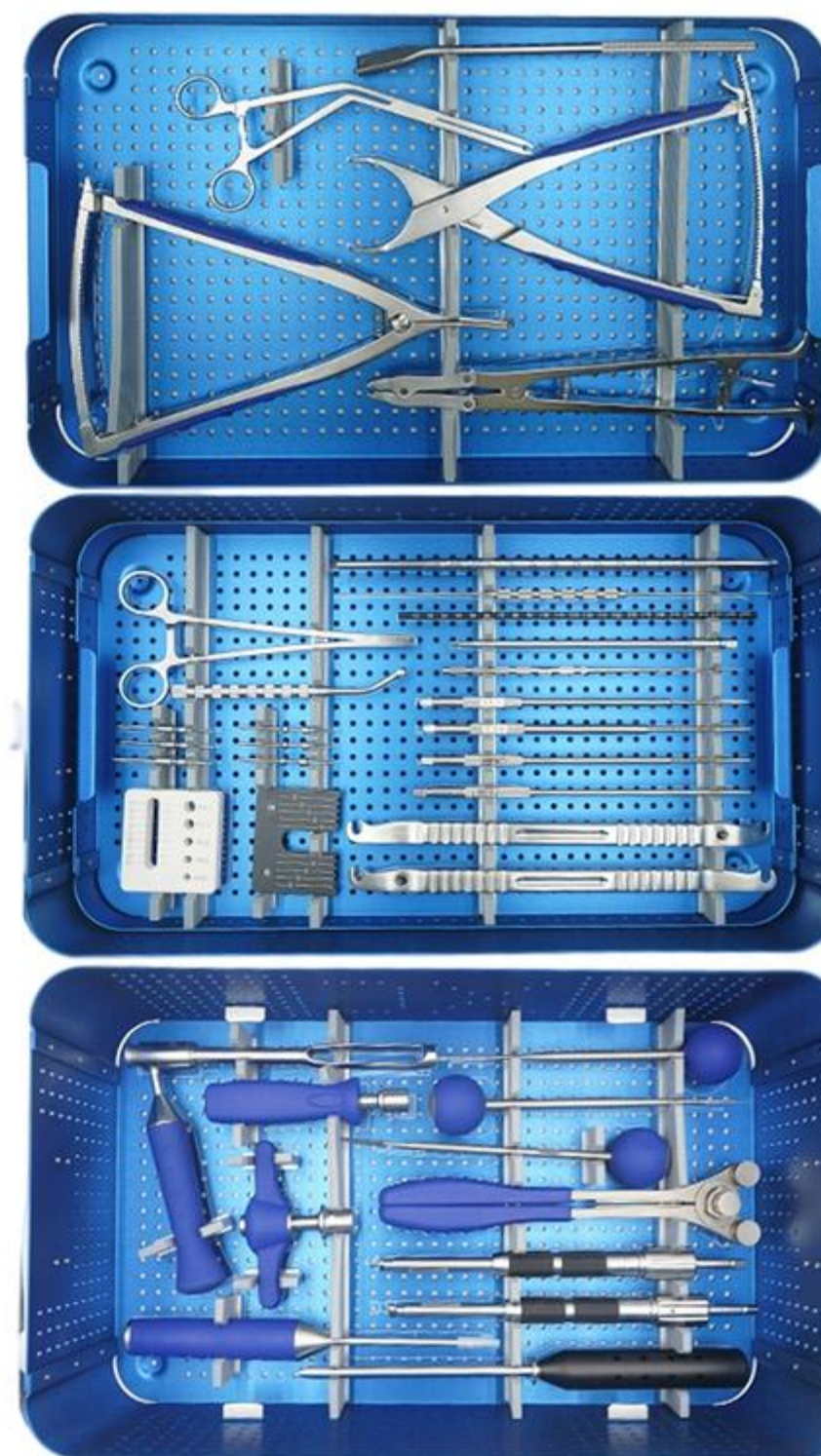
Gradient Titanium Rod



REF	Specification
R6ZDGZ6030	6.0*30mm
R6ZDGZ6040	6.0*40mm
R6ZDGZ6050	6.0*50mm
R6ZDGZ6060	6.0*60mm

Instrument Infommation

6.0mm Spinal Pedicle Screw System Instrument Set



RQ60JNGD01

REF	Description	Qty.
RQ6JTWQL	In-situ Rod Bender (L)	1
RQ6JTWQR	In-situ Rod Bender (R)	1
RQ6JSDQW	Screwdriver for Polyaxial Screw	1
RQ6JSDQD	Screwdriver for Monoaxial Screw	1
RQ6JDWZDQ	Screw Tab Breaker	1
RQ6JSZ45	Tap 4.5	1
RQ6JSZ55	Tap 5.5	1
RQ6JSZ60	Tap 6.0	1
RQ6JSZ65	Tap 6.5	1
RQ6JDKBS	Counter Sleeve	1
RQ6JCBQ	Rod Holding Forceps	1
RQJZKSBSF	Straight Quick Coupling Handle (square connection)	1
TYMB60300G	Mould Rod 300	1
RQ6JXBSW5	Rod Twist Wrench SW5.0	1
RQJXZQ	Fixation Pin Holder	1
RQJQXZ	Ball-type Fixation Pin	4
RQJZXZ	Pillar-type Fixation Pin	4
RQ6JTKSBSF	T-handle Quick Coupling Handle	1
RQ6JZBQ	Rod Twister 6.0	1
RQJZKLQ32	3.2 Straight Pedicle Probe	1
RQJWKLQ32	3.2 Curved Pedicle Probe	1
RQJWKLQ	Curved Pedicle Probe	1
RQ6JKLZ	AWL	1
RQJSTZ	Double-Head Probe	1

REF	Description	Qty.
RQ6JZSJSW5	Tightening Screwdriver SW5.0	1
RQ6JYJSW5	Set Screw Holding Screwdriver SW5.0	1
RQJYTZ	Single-head Probe (stiff)	1
RQJWBQ	Rod Bender	1
RQ6JYSQ	Compressor	1
RQ6JCKQ	Spreader	1
RQ6JHCLC	Crosslink Measurement	1
RQ6JLDCLC	Screw Measurement	1
RQ5JHSW35	Crosslink Screwdriver SW3.5	1
RQ5JZHSW35	Self-retaining Crosslink Screwdriver SW3.5	1
RQ5JCYBQ	C-type Rod Persuader	1
RQ5JHCBQ	Crosslink Rod Holding Forceps	1
RQ6JMJHL	Instrument Box	1

Optional

REF	Specification	Qty.
RQ6JCTT	Persuader Sleeve	1
RQ6JWFQ	Persuader	1
RQJJLSF	Spreader	1
RQ6JCWYBQ	Rod Pushing Forcep	1
RQJ12NMSF	12 N.m Torque Wrench	1