Surgical Technique
Guide and Ordering Information

Favored Angle Screw
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### SURGICAL TECHNIQUE

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INTRODUCTION

*DePuy Spine continues to support the goal of expanding the spine surgeon’s options for the treatment of spinal disorders. The EXPEDIUM® Favored Angle screw is an innovative solution for the correction of both complex deformity and degenerative pathologies. The Favored Angle screw design takes three proven pedicle screw technologies and combines them into one powerful implant, all while maintaining compatibility with the EXPEDIUM Spine System. The uncompromising versatility of the EXPEDIUM brand of products allows surgeons to select from a wealth of innovative technologies, such as the Favored Angle screw, and apply it to their individual technique for optimal correction.*

*This guide will provide step-by-step descriptions of segmental translation and derotation using the Favored Angle screw. Furthermore, this guide will address other commonly used techniques, which have proven successful with the innovative Favored Angle screw technology.*

*The EXPEDIUM Brand of products once again redefines control of complex deformity and degenerative pathologies through innovative technology introductions.*

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**REDUCTION TABS**

**DUAL LOCKING MECHANISM**

**FAVORED ANGLE**

Up to 77.7° total angulation based on screw size

The Favored Angle screw features a Dual Lead thread design, which allows the screw to advance twice as far per turn, when compared to standard screws.
SCREWDRIVER APPLICATION AND SCREW PLACEMENT

EXTENDED TAB DI QUICK-CONNECT SCREWDRIVER APPLICATION

- Place the tip of the screwdriver into the head of the screw. Slide the screwdriver sleeve down and thread into the reduction tabs and screw head. To disengage, unthread the screwdriver sleeve.

SCREW PLACEMENT

- Use head adjuster to place head of screw in desired location (Figure 1).

NOTE:

The screw head should sit slightly above the posterior vertebral cortex to allow polyaxial movement and to receive the benefit of the favored angle. Alternatively, the pedicle broach (reamer) can be used to create additional space.

NOTE:

The notch/etch on the screw head indicating the orientation of the favored angle should be placed lateral to the pedicle to ensure the head can angulate away from the spinous process and allow translation reduction (Figure 2).

See Pedicle Targeting Technique, EXPEDIUM Surgical Technique and Pedicle Screw Insertion Technique for details on pedicle targeting, preparation, and insertion.
SEGMENTAL TRANSLATION

Segmental Translation is a widely used maneuver for the correction of coronal deformity (Figure 3). The main goal of this technique is to segmentally bring the spine to the contoured rod, allowing for coronal correction to occur. The use of the EXPEDIMUM Favored Angle Screw at each level may minimize the potential for screw pull out during reduction maneuvers since the strain forces are spread over multiple levels. This maneuver can be performed in conjunction with other techniques to allow for sagittal, coronal and axial correction.

FIGURE 3
Contour the rods for both the concave and convex sides of the construct.

- Titanium and CoCr Alloy rods will require different amounts of force to achieve desired kyphosis or lordosis. Some degree of hyperkyphosis can be built into the concave rod to account for flexibility in the material and stiffness of the curve during the correction maneuver and may help to pull the lordotic apex of the concavity out of the chest. Conversely, the convex rod can be undercontoured to aid in reducing the rib hump and derotating the apex.

Insert the concave rod into the proximal and distal anchors. If rod has both kyphosis and lordosis, it may be possible to only insert into distal anchor to begin.

Insert the setscrews into the anchor points using the DI Inserter and tighten outer setscrew (purple color ring) to lock the trajectory of the screw shank and fix the position of the screw head.

**NOTE:**
The inner setscrew should not advance beyond the underside of the outer setscrew. This condition prevents:
- The outer setscrew from locking the poly head in place for correction maneuvers.
- Translation along the rod during compression and distraction maneuvers.
- The ability of the DI Inserter to properly engage with the setscrew.
After proximal and/or distal foundations are secured, the spine is translated to the rod segmentally by reducing the rod into the reduction tabs using the setscrews (Figure 4, 5, 6). Figure 6 illustrates segmental reduction. As each setscrew is reduced into the screw head, the Favored Angle in the adjacent level is brought closer to the rod.

**NOTE:**
The favored angled allows for an added 15° of lateral angulation of the screw head, which aids in capturing the rod at the apex of the curve.
Typically the sagittal contour of the rod is still in the coronal plane, although it is now fully captured. The rod may not be fully seated in the screw. A Cotrel Dubousset rod rotation maneuver can be performed at this point to correct the coronal deformity with appropriate sagittal contour.

- Rod holders can be used to rotate the rod, or alternatively, use of the hex wrench on the hex end of the rod along with the rod holders allows the rod to be rotated to restore sagittal alignment (Figure 7).

- In order to reduce the rib prominence, it may help to have an assistant push down on the convex ribs and the convex screws. The use of alignment guides assembled on the screw heads are used to rotate the vertebral bodies into proper axial alignment. This step may help to reduce the rib prominence.

- Additional alignment guides can be placed at the neutral vertebral segment of the construct to ensure opposing rotation is not introduced in the lumbar spine.
Additional correction, such as segmental derotation can be performed at this point (Figure 8).

- Insert second contoured rod on convex side.
- Lock rod into place using DI setscrew and final tighten all outer setscrews. The Dual Locking feature of the screw turns the polyaxial screw into a fixed angle screw when the outer portion of the set screw is fully tightened, aiding in derotation maneuvers.

NOTE:
Coinciding multi-level rod capturing distributes load throughout the construct and reduces the risk of screw pullout during translation.
SEGMENTAL DERO TATION

Segmental Derotation can be performed as the sole correction maneuver, or can be used in addition to other correction techniques. In cases where there is rotational deformity of the spine, axial correction may be needed, which can be addressed by this technique.

Implant the sagittally contoured concave rod and capture with setscrews. Most setscrews should be left loose since lengthening of the spine is expected at each level that will be segmentally derotated. Only the setscrews in the distal and proximal neutral vertebra should be tightened.

• Two rods can be implanted at this time, however Direct Vertebral Rotation (DVR) is most effective when done with only a single rod captured in the screw heads.

• Advance the purple outer portion of all setscrews to lock the head of the screws in the desired location. This will not lock the screw onto the rod, but rather provide for rotation of the screw around the rod for derotation, as well as compression and distraction (Figure 9 & 10).

NOTE:
The inner set screw should not be advanced beyond the underside of the outer setscrew. This condition prevents:

• The outer setscrew from locking the polyaxial head in place for correction maneuvers.

• Translation along the rod during compression and distraction maneuvers.

• The ability of the DI Inserter to properly engage with the setscrew.
Apply two Alignment Guides (Facilitator Tubes) to the distal anchors of the neutral segment. Place another two alignment guides on the next proximal level.

Derotate proximal vertebra to neutral and tighten setscrews.

Repeat previous steps, moving proximally toward the apex (Figure 11 & 12).
The long tabs allow loose approximation of the contralateral rod during this maneuver, and they allow DVR to be repeated several times during the correction without having to remove the rod.

Repeat at each level until vertebra match the neutral proximal and distal vertebra.

At the apex, Apical Derotation can be performed to achieve greater correction.

• In conjunction with DVR, the apical screws on the concave side can be locked, while the convex side rod is implanted.

• While reducing the rod using the reduction tabs, the concave pedicle screw will be brought up to the rod. While performing this maneuver, correction of axial rotation may be facilitated by pushing down on the convex side of the rib hump (Figure 13). This will both augment and maintain vertebral rotation.

• Multiple Alignment Guides (Facilitator Tubes) or Rotators can be used in an effort to distribute the rotational forces across multiple pedicles.

Compression or distraction can be performed segmentally at this point if needed, as the Favored Angle screws allow for parallel compression/distraction on the rod.

Gradual distraction from the lumbar levels to the thoracic levels on the concavity can aid in additional coronal correction. Conversely, gradual compression from the lumbar spine to the thoracic spine on the convexity can aid in additional coronal correction. If necessary, in-situ benders can be used.

Once correction has been attained, final tighten all setscrews with the appropriate torque-limiting wrench.
FIN AL TIGHTENING

Final tightening of the outer setscrew is performed with the Dual Innie Final Tightener with Indicator and final tightening of the inner setscrew is performed with the X25 Final Tightener (per standard EXPEDIUM final tightening techniques).

The shaft of the DI Final Tightener with Indicator is inserted through the Rod Stabilizer (anti-torque device) and into the castle-nut feature of the setscrew. The Rod Stabilizer is then slid down over the screw head and onto the rod (Figure 14).

FIGURE 14
• Rotate the T-Handle clockwise until the white guidelines align indicating that 8 Newton meters or 80 in-lb has been applied (Figure 15).

![Figure 15](image)

**NOTE:**
The final tightener for the outer setscrew does not “click”. There are markings on both sides of the tightener to indicate the proper amount of force to be used. Also, the outer setscrew can be “white-knuckle” tightened if preferred.

Final tightening of the inner setscrew is preformed with the Hexlobe Shaft inserted into the T-Handle Torque Wrench, set to 80 in-lb.

• The T-Handle is rotated clockwise until it clicks and resistance is no longer evident.

Once Final Tightening is complete, reduction tabs can be broken off using the Reduction Tab Remover.

*See EXPEDIUM Surgical Technique for more details on Final Tightening.*
ADDITIO N A L TEC HNIQUES A N D USES

LUMBAR LEVELING & CONVERGING SCREWS

Particularly in degenerative deformities and where the surgeon may wish to save mobile segments, it may be useful to compress or distract screws on the rod to level a vertebra. This can be achieved without losing vertebral derotation.

- Implant screws and use the notch to locate the side of the favored angle.

- Position screw head so that favored angle is medial, allowing for easier placement of rod and setscrew. Medial placement of the screw head will alleviate the struggle with soft tissue impeding on the converging screws in the lower lumbar spine.

- Capture and reduce the rod using the reduction tabs, leaving inner portion of setscrew loose.

- Ensure that outer portion of setscrew is locked, which will lock the trajectory of the screw shank, while allowing for true parallel compression or distraction of the vertebral level (Figure 16 & 17). This can be a useful maneuver to achieve a complete discectomy, in a transforaminal or posterior lumbar interbody fusion, to minimize the effect of intervertebral “fish-mouth” or to place uniform load on the subsequent bone graft.

- Next, compress or distract as needed and final tighten inner setscrew.
PROXIMAL OVERCONTOURING OR HYPERKYPHOSIS

If it is felt that hyperlordosis is being created and proximal junctional kyphosis is a concern, the rod can be overcontoured to allow for flattening after placement and correction (Figure 18 & 19).

Use the extended tabs to more easily capture the overcontoured rod into the screws.

The same maneuver can be used to reduce kyphosis by cantilevering the rods into the distal lumbar reduction screws.
PUMPHANDLE / CANTILEVER

This maneuver is particularly useful for large and stiff curves and for kyphotic deformities. A CoCr Alloy rod may be used in place of titanium if increased rod stiffness is desirable.

- Place rod in proximal screws and tighten outer set screws to lock head in place.
- Cantilever rod into distal screws using rod holder. Extended tabs should allow for easy delivery of the rod to the screw (Figure 20 & 21).
- Place set screws in rest of screw heads to capture and lock rod into place.
REMOVAL/REVISION INSTRUCTIONS

REMOVAL PROCEDURE

If a decision is made to remove the implants after solid fusion occurs, the following steps should be taken after the implant is exposed:

1. Clean debris/tissue from the setscrew.
2. Loosen the setscrews and remove.
3. Remove the rod to expose the head of the screw. Perform necessary revision, if applicable.
4. Insert screwdriver into screw head and to back screw out of the pedicle.
## ORDERING INFORMATION

### IMPLANTS

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### INSTRUMENT CASES / TRAYS

The following instruments, cases and trays are specific to the Favored Angle screw.

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INDICATIONS

The EXPEDiUM Spine System is intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of acute and chronic instabilities or deformities of the thoracic, lumbar and sacral spine.

The EXPEDiUM Spine System is intended for noncervical pedicle fixation and nonpedicle fixation for the following indications: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies); spondylolisthesis, trauma (i.e., fracture or dislocation); spinal stenosis; curvature (i.e., scoliosis, kyphosis, and/or lordosis); tumor, pseudarthrosis; and failed previous fusion in skeletally mature patients.

CONTRAINDICATIONS

Disease conditions that have been shown to be safely and predictably managed without the use of internal fixation devices are relative contraindications to the use of these devices. Active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation. Severe osteoporosis is a relative contraindication because it may prevent adequate fixation of spinal anchors and thus preclude the use of this or any other spinal instrumentation system. Any entity or condition that totally precludes the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia is a relative contraindication. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, patients who because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism, or drug abuse, may place undue stresses on the implant during bony healing and may be at higher risk for implant failure.

WARNINGS, PRECAUTIONS, AND POSSIBLE ADVERSE EFFECTS CONCERNING TEMPORARY METALLIC INTERNAL FIXATION DEVICES

Following are specific warnings, precautions, and possible adverse effects that should be understood by the surgeon and explained to the patient. These warnings do not include all adverse effects that can occur with surgery in general, but are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

WARNINGS

1. CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for satisfactory fixation is increased by the selection of the proper size, shape, and design of the implant. While proper selection can help minimize risks, the size and shape of human bones present limitations on the size, shape and strength of implants. Metallic internal fixation devices cannot withstand activity levels equal to those placed on normal healthy bone. No implant can be expected to withstand indefinitely the unsupported stress of full weight bearing.

2. IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION. Internal fixation appliances are load-sharing devices which are used to obtain alignment until normal healing occurs. If healing is delayed, or does not occur, the implant may eventually break due to metal fatigue. The degree or success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of this risk of implant failure.

3. MIXING METALS CAN CAUSE CORROSION. There are many forms of corrosion damage and several of these occur on metals surgically implanted in humans. General or uniform corrosion is present on all implanted metals and alloys. The rate of corrosive attack on metal implant devices is usually very low due to the presence of passive surface films. Dissimilar metals in contact, such as titanium and stainless steel, accelerate the corrosion process of stainless steel and more rapid attack occurs. The presence of corrosion often accelerates fatigue fracture of implants. The amount of metal compounds released into the body system will also increase. Internal fixation devices, such as rods, hooks, etc., which come into contact with other metal objects, must be made from like or compatible metals.

4. PATIENT SELECTION. In selecting patients for internal fixation devices, the following factors can be of extreme importance to the eventual success of the procedure.

A. The patient's weight. An overweight or obese patient can produce loads on the device that can lead to failure of the appliance and the operation.

B. The patient’s occupation or activity. If the patient is involved in an occupation or activity that includes heavy lifting, muscle strain, twisting, repetitive bending, stooping, running, substantial walking, or manual labor, he/she should not return to these activities until the bone is fully healed. Even with full healing, the patient may not be able to return to these activities successfully.

C. A condition of senility, mental illness, alcoholism, or drug abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the appliance, leading to implant failure or other complications.

D. Certain degenerative diseases. In some cases, the progression of degenerative disease may be so advanced that it may substantially decrease the expected useful life of the appliance. For example, in cases where spinal fixation devices can only be considered a delaying technique or temporary remedy.

E. Foreign body sensitivity. The surgeon is advised that no preoperative test can completely exclude the possibility of sensitivity or allergic reaction. Patients can develop sensitivity or allergy after implants have been in the body for a period of time.

F. Smoking. Patients who smoke have been observed to experience higher rates of pseudarthrosis following surgical procedures where bone graft is used. Additionally, smoking has been shown to cause diffuse degeneration of intervertebral discs. Progressive degeneration of adjacent segments caused by smoking can lead to late clinical failure (recurring pain) even after successful fusion and initial clinical improvement.

PRECAUTIONS

1. SURGICAL IMPLANTS MUST NEVER BE REUSED. An explanted metal implant should never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which may lead to early breakage. Reuse can compromise device performance and patient safety. Reuse of single use devices can also cause cross-contamination leading to patient infection.

2. CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT. Contouring of metal implants should only be done with proper equipment. The operating surgeon should avoid any notching, scratching or reverse bending of the devices when contouring. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant. Bending of screws will significantly decrease the fatigue life and may cause failure.

3. CONSIDERATIONS FOR REMOVAL OF THE IMPLANT AFTER HEALING. If the device is not removed after the completion of its intended use, any of the following complications may occur: (1) Corrosion, with localized tissue reaction or pain; (2) Migration of implant position resulting in injury; (3) Risk of additional injury from postoperative trauma; (4) Bending, loosening, and/or breakage, which could make removal impractical or difficult; (5) Pain, discomfort, or abnormal sensations due to the presence of the device; (6) Possible increased risk of infection; and (7) Bone loss due to stress shielding. The surgeon should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid fracture. If the patient is older and has a low activity level, the surgeon may choose not to remove the implant thus eliminating the risks involved with a second surgery.

4. ADEQUATELY INSTRUCT THE PATIENT. Postoperative care and the patient's ability and willingness to follow instructions are among the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant, and instructed to limit and restrict physical activities, especially lifting and twisting motions and any type of sports participation. The patient should understand that a metallic implant is not as strong as normal healthy bone and could loosen, bend and/or break if excessive demands are placed on it, especially in the absence of complete bone healing. Implants displaced or damaged by improperly applied activities may migrate and damage the nerves or blood vessels. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

5. CORRECT PLACEMENT OF ANTERIOR SPINAL IMPLANT. Due to the proximity of vascular and neurologic structures to the implantation site, there are risks of serious or fatal hemorrhage and risks of neurologic damage with the use of this product. Serious or fatal hemorrhage may occur if the great vessels are eroded or punctured during implantation or are subsequently damaged due to breakage of implants, migration of implants or if pulsatile erosion of the vessels occurs because of close apposition of the implants.
4.5 Spine System
5.5 Spine System
6.35 Spine System
SFX® Cross Connector System
Anterior Spine System
VIPER® 2 System