INTRODUCTION


EXPEDIUM Offset’s technique simplifying designs maximize performance to meet the challenge of even the most difficult pathologies.

Developed for comprehensive, multi-pathology application, EXPEDIUM Offset seamlessly integrates an unprecedented breadth of versatile and complementary components in a single implant system.

To spine surgeons trained in the treatment of complex spinal pathologies, the EXPEDIUM Offset System works in harmony with the EXPEDIUM family of in-line implants and offers uncompromising versatility to customize constructs based on the individual patient and pathology. The EXPEDIUM Offset System was developed by DePuy Spine, the company that pioneered offset technology.

EXPEDIUM OFFSET: AN EVOLUTION IN ADAPTABILITY

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DEVICE DESCRIPTION

The EXPEDIUM Spine System is a 5.5mm and 6.35mm rod based system offered in both titanium and stainless steel. Both systems consist of the following:

- Monoaxial screws
- Polyaxial screws
- Uni-planar screws
- Reduction screws
- Reduction hooks
- Hooks
- Extended tab implants
- Sacral extenders
- Lateral connectors
- Washers

In addition, the EXPEDIUM OFFSET Spine System is a 5.5 and 6.35mm rod and plate system, offered in both titanium and stainless steel. EXPEDIUM OFFSET will also include the following:

- Fixed bolts
- Polyaxial bolts
- Closed screws
- Hooks
- Slotted connectors
- Plates
- Nuts
- Washers
- Drop-entry connectors
- Modular cross connectors
- Transverse rod connectors
- Wires
IMPLANT TERMINOLOGY

For the purposes of clarifying terms used throughout this surgical technique, details follow on key implant features of the EXPEDIUM Offset System.

**FIXED BOLTS**

- **BOLT POST**
- **MACHINE THREAD** 1/4"-28
- **10mm DISTAL TAPER**
- **INTERNAL DRIVE FEATURE (X20)**
- **INTERNAL DRIVE FEATURE (X20)**

**POLYAXIAL BOLTS**

- **BOLT POST**
- **LOCKING WASHER**
- **DUAL LEAD THREAD PATTERN**
- **10mm DISTAL TAPER**
- **LOCKING WASHER**
- **INTERNAL DRIVE FEATURE (X20)**
DUAL LEAD THREAD

All fixed and polyaxial bolts have a dual lead thread pattern. The dual lead thread advances twice as quickly as a traditional single lead thread.

SLOTTED CONNECTORS AND DUAL DIAMETER (DDVHG) TECHNOLOGY

The standard slotted connectors in the EXPEDIUM Offset System feature a dual diameter feature enabling use with either a 5.5mm or 6.35mm rod.
**IMPLANT ASSEMBLIES**

EXPEDIUM Offset provides multiple options for angulation. The first image shows the fixed bolt with no washers, and no angulation. The second image shows a fixed bolt, assembled with polyaxial washers above and below the slotted connector, providing 25° of angulation. Finally, the third image shows the EXPEDIUM Offset polyaxial bolt, offering an average 60° cone of angulation. The lowered rod slot of the slotted connector paired with the polyaxial bolt provides lower profile constructs.

**CONSTRAINED PLATES**

Constrained plates offer a single hole to avoid anatomy and the superior facet.
ANGULATING CONNECTORS

A new addition to the EXPEDİUM Offset System is the angulating connector, allowing the rod slot to rotate relative to the implant placement for desired connector positioning.

LOCKING NUTS

All locking nuts in the EXPEDİUM Offset System utilize an 8mm hexagonal drive feature.
PEDICLE PREPARATION
Pedicle preparation is performed utilizing a selection of awls, pedicle probes, ball tip feelers and bone taps.
Probes and bone taps are marked to indicate appropriate length to aid in proper bolt selection.

All bolts are self-tapping. Taps are provided for surgeon preference, but are not required.

PROBES
Various probe options are offered based on patient anatomy and surgeon preference.

FIXED BOLT DRIVER INSERTION
The fixed bolt driver is placed over the bolt post until firmly seated.
Once the pedicle is prepared and the correct fixed bolt length and diameter are selected, the fixed bolt is inserted into the pedicle.

Pedicle preparation and implantation of the desired levels is completed with the appropriate fixed bolt lengths and diameters based on patient anatomy and surgeon preference.
If polyaxial motion is desired, polyaxial washers are inserted “dome down.”

See Washer Directions on page 14.

Appropriate style slotted connectors are chosen for optimal connection to each bolt.

The slotted connectors are loosely loaded onto the selected length rod with the nurse’s wrench and placed over the bolt posts.

Where polyaxial washers were placed on bolts below the slotted connectors, a second washer must be placed “dome up” on each bolt on top of the slotted connector.

Spacer washers are not placed above slotted connectors.
LOCKING NUT APPLICATION

Locking nuts are loaded from the locking nut and washer caddy. Nuts can be loaded onto a nut inserter, nut driver or intermediate/final tightening torque shaft paired with the desired handle.

With the slotted connectors and desired polyaxial washers in place, the locking nuts are threaded onto the bolts.
SLOTTED CONNECTOR FINAL TIGHTENING – STEP ONE

Final tightening is first performed on the body of the slotted connector to ensure proper seating of the rod.

The hex lobe shaft is inserted into the T-handle torque wrench, which is set to 80 inch pounds of torque.

The X25 shaft is inserted thru the closed connection stabilizer and then into the set screw of the slotted connector body.

The stabilizer is slid down over the body of the slotted connector and onto the rod.

The T-handle is then rotated clockwise until it clicks and resistance is no longer evident.

The closed connection stabilizer is used to prevent torsion of the construct during final tightening.

The T-handle torque wrench is always set to 80 inch pounds of torque for set screw tightening.

The X-25 set screws in the slotted connectors should always be torqued before final tightening of the nuts on the bolt posts.
Set at 80 inch pounds of torque, the T-handle is then rotated clockwise until it clicks and resistance is no longer evident.

SLOTTED CONNECTOR FINAL TIGHTENING – STEP TWO: LOCKING NUT FINAL TIGHTENING

The red T-handled hex lobe driver (X20) is placed thru the cannula of the T-handle torque wrench to prevent bolt advancement into the pedicle.
**POST CUTTING**

If a fixed reduction bolt was used in the procedure, the post should be cut with the supplied bolt post cutter. The retained bolt post is then ejected from the cutter using the supplied ejection pin and discarded.

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**NOTE:**

A total of two washers (two spacer washers, or one spacer washer and one polyaxial washer) will fit below a slotted connector on a pedicle bolt. If additional washers are required, a reduction bolt must be used.

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**WASHER DIRECTIONS**

**Polyaxial “Dome Up”**

Where a polyaxial washer has been placed beneath a spine plate, one should be placed above in the opposite orientation, or “dome up” to mate with the bottom of the lock nut.

**Polyaxial “Dome Down”**

Beneath a smooth spine plate, a single polyaxial washer may be placed “dome down” into the integral nut of a pedicle or reduction bolt, or the receiving portion of a spacer washer.

**Spacer**

Spacer washers may only be placed beneath a slotted connector, directly into the integral nut of a pedicle or reduction bolt.

**Spacer washers may not be placed on top of polyaxial washers.**
PEDICLE PREPARATION

Pedicle preparation is performed utilizing a selection of awls, pedicle probes, ball tip feelers and bone taps.

Probes and bone taps are marked to indicate appropriate length to aid in proper bolt selection.

All bolts are self-tapping. Taps are provided for surgeon preference, but are not required.

PROBES

Various probe options are offered based on patient anatomy and surgeon preference.

POLYAXIAL BOLT DRIVER ASSEMBLY

The requested polyaxial bolt is taken from its caddy and aligned with the polyaxial bolt driver.

The polyaxial bolt driver’s tip should be moved down the post of the bolt. When engaged, the sleeve of the polyaxial bolt driver is rotated clockwise to tighten the polyaxial bolt to the driver. Attention should be made to confirm that the bolt is securely in place and the shaft of the bolt is oriented correctly.
**POLYAXIAL BOLT INSERTION**

Once the pedicle is prepared and the correct polyaxial bolt implant length and diameter are selected, the polyaxial bolt is inserted into the pedicle.

To adjust the height of the bolt in the anatomy, it may be rotated counter clockwise.

Once proper elevation above the pedicle is achieved, the polyaxial bolt head can be adjusted and positioned using the head adjuster (the fixed bolt driver located in the bolt insertion tray).

Pedicle preparation and implantation of the desired levels is completed with the appropriate polyaxial bolt lengths and diameters based on patient anatomy and surgeon preference.
SLOTTED CONNECTOR PLACEMENT ON POLYAXIAL BOLTS

Appropriate style slotted connectors are chosen for optimal connection to each bolt.

The slotted connectors are loosely loaded onto the selected length rod and placed over the threaded posts of the bolts.

LOCKING NUT APPLICATION

Locking nuts are loaded from the locking nut and washer caddy. Nuts can be loaded onto a nut inserter, nut driver or intermediate/final tightening torque shaft paired with the desired handle.
The locking nuts are threaded onto the bolts.
SLOTTED CONNECTOR FINAL TIGHTENING – STEP ONE

Final tightening is first performed on the body of the slotted connector to ensure proper seating of the rod.

The hex lobe shaft is inserted into the T-handle torque wrench, which is set to 80 inch pounds of torque.

The X25 shaft is inserted thru the closed connection stabilizer and then into the set screw of the slotted connector body.

The stabilizer is slid down over the body of the slotted connector and onto the rod.

The T-handle is then rotated clockwise until it clicks and resistance is no longer evident.

The closed connection stabilizer is used to prevent torsion of the construct during final tightening.

The T-handle torque wrench is always set to 80 inch pounds of torque for set screw tightening.

The X-25 set screws in the slotted connectors should always be torqued before final tightening of the nuts on the bolt posts.
SLOTTED CONNECTOR FINAL TIGHTENING – STEP TWO

The red T-handled hex lobe driver (X20) is placed thru the cannula of the T-handle torque wrench to prevent bolt advancement into the pedicle.

Set at 80 inch pounds of torque, the T-handle is then rotated clockwise until it clicks and resistance is no longer evident.
Hook sites are chosen preoperatively or intra-operatively by the surgeon.

The appropriate hook starter is utilized based on surgeon preference to prepare each selected hook site.

**EXPEDİUM OFFSET HOOKS**

**HOOK SITE PREPARATION**

Pedicle Hook Starters

Laminar Hook Starters

Transverse Process Hook Starters
PEDICLE HOOKS

The hook driver can be used in conjunction with the open hook holder to position the pedicle hook.

The rod is captured into the pedicle hook by inserting the set screws.

Final tightening is performed, utilizing the open hook stabilizer, and tightening the set screw to 80 inch pounds.
TRANSVERSE PROCESS HOOKS
The hook driver can be used in conjunction with the open or closed hook holder to position an open or closed hook on the transverse process.

Open or closed hooks may be used according to surgeon preference.

CLOSED HOOK PLACEMENT
Ensure closed hook body is clear of the set screw prior to insertion of the rod.

The rod is placed through the hook. Compression may be required. Compression and distraction maneuvers are facilitated thru interim tightening and loosening of set screw.

When final hook placement is completed, it is followed by final tightening utilizing the closed hook stabilizer and tightening to 80 inch pounds of torque.

OPEN HOOK PLACEMENT AND TIGHTENING
Open hook placement is consistent with placement of closed hooks; however, the rod is captured into the open hook by inserting the set screw.

Compression and distraction can be facilitated by interim tightening of the set screw and utilizing the appropriate compressor and distractor.

Final tightening is also completed to 80 inch pounds of torque. Counter-torque is applied using the open hook stabilizer.
LAMINAR HOOK PLACEMENT

The hook driver can be used in conjunction with the open or closed hook holder to position an open or closed hook on the lamina.

Open or closed hooks may be used according to surgeon preference.

The X25 final tightener is placed in the hook stabilizer for closed hooks (shown) or open hooks.

The stabilizer is lowered over the hook and final tightening is performed to 80 inch pounds of torque.

REMOVAL INSTRUCTIONS

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 locking nuts and set screws.

2. Loosen locking nuts on the bolt posts with an 8mm wrench after placing the T-20 counter torque down the bolt post, and remove.

3. Once the locking nuts are loose, the rods and slotted connectors or plates can be removed.

4. If necessary, the set screws on the slotted connectors may be loosened with the X-25 screwdriver.

5. With polyaxial or fixed bolt heads visible, utilize the appropriate screwdriver to back the screw out of the pedicle.
IMPLANT OPTIONS

FIXED BOLTS

FIXED REDUCTION BOLTS

POLYAXIAL BOLTS

POLYAXIAL REDUCTION BOLTS

FIXED BOLTS

- 4.35 mm
- 5.00 mm
- 6.00 mm
- 7.00 mm
- 8.00 mm
- 9.00 mm
SLOTTED CONNECTORS (DUAL DIAMETER 5.5 mm AND 6.35 mm)

- Standard
- Extended
- Downsized
- Angled

SLOTTED CONNECTORS FOR POLYAXIAL BOLTS (DUAL DIAMETER 5.5 mm AND 6.35 mm)

- Standard
- Extended
- Downsized

ANGULATING CONNECTORS

- 5.5 mm
- 6.35 mm

TWISTERS
**EXPEDIUM OFFSET SURGICAL TECHNIQUE**

MCC

Closed Hooks (All sizes available in 5.5 mm and 6.35 mm)

Closed Pedicle

Closed Narrow

Closed Wide Blade

Drop Entry Connector
OPEN HOOKS

Open Pedicle 5.5 mm

Open Pedicle 6.35 mm

Open Narrow 5.5 mm

Open Narrow 6.35 mm

Open Wide 5.5 mm

Open Wide 6.35 mm
INDICATIONS
The EXPEDİUM Spıne 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 EXPEDİUM Spıne 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 osteoporosis 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 stress 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 risk, 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 of success of union, loads produced by weight bearing, and activity levels will, among other conditions, dictate the longevity of the implant. Notsches, scratches or bending of the implant during the course of surgery may also contribute to early failure. Patients should be fully informed of the risks 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 advancing at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopaedic devices can only be considered a delaying technique or temporary remedy.

E. Foreign body sensitivity. The surgeon is advised that no preparative 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 implanted 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 improper 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.
Offset System
4.5 Spine System
5.5 Spine System
6.35 Spine System
Vertebral Body Derotation Set
SFX® Cross Connector System
Anterior Spine System
VIPER® 2 System

Limited Warranty and Disclaimer: DePuy Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS: In the USA, this product has labeling limitations. See package insert for complete information.

CAUTION: USA Law restricts these devices to sale by or on the order of a physician.

To order in the US, call DePuy Spine Customer Service (1-800-227-6633).

Not all products are currently available in all markets.

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