Building upon decades of cumulative design history, clinical experience and biomechanical performance of the VSP® Spine System, TIMX® Low Back System, and MONARCH® Spine System, EXPEDIUM® Plates represents the combination of DePuy Spine’s high performing foundations with revolutionary new technology.

EXPEDIUM Plates provide simplified designs while maximizing performance to meet the challenge of even the most difficult pathologies. With Nested and Smooth Plate options to be paired with Fixed or Polyaxial bone anchors, EXPEDIUM Plates offers every option available today for plate/implant integration.

The EXPEDIUM Plates System was developed by DePuy Spine, the company who pioneered plate technology.

**EXPEDIUM PLATES: BACK TO THE BASICS**

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**SURGEON DESIGN TEAM**

- **Behrooz A. Akbarnia, MD**
  - San Diego Center for Spinal Disorders
  - La Jolla, California

- **Oheneba Boachie-Adjei, MD**
  - Hospital for Special Surgery
  - New York, New York

- **Douglas Burton, MD**
  - The University of Kansas Hospital
  - Kansas City, Kansas

- **Samuel Chewning, MD, MBA**
  - Carolina Neurosurgery and Spine Center
  - Charlotte, North Carolina

- **Munish Gupta, MD**
  - UC Davis Medical School
  - Sacramento, California

- **Nathan Lebwohl, MD**
  - University of Miami
  - Miami, Florida

- **Takachika Shimizu, MD**
  - Gunma Spine Center
  - Gunma, Japan

- **Roger Sørensen, MD**
  - Oslo Universitetssykehus
  - Rikshospitalet, Norway

- **Theodore Wagner, MD**
  - University of Washington Medical School
  - Seattle, Washington
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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**
- **Machined Thread Pattern**
- **Dual Lead Thread Pattern**
- **Bolt Drive Feature**
- **10mm Distal Taper**
- **Internal Drive Feature (X20)**

**POLYAXIAL BOLTS**

- **Bolt Post**
- **Internal Drive Feature (X20)**
- **10mm Distal Taper**
- **Dual Lead Thread Pattern**
- **Locking Washer**
**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.
EXPEDIUM PLATES SURGICAL TECHNIQUE

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.

CONSTRANGED PLATES

Constrained plates offer a single hole to avoid anatomy and the superior facet.
ANGULATING CONNECTORS
A new addition to the EXPEDIMUM 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 EXPEDIMUM Offset System utilize an 8mm hexagonal drive feature.
EXPENDIUM OFFSET FIXED BOLTS WITH SPINE PLATES

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 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.

**POLYAXIAL WASHER INSERTION**

If smooth plates are chosen, polyaxial washers may be inserted “dome down” if desired.

See **Washer Directions** on page 14.
PLATE SELECTION AND PLACEMENT

With washer selection completed, measurement is taken for selection of the appropriately sized smooth or nested plate.

If desired, the plates may be contoured using a plate bender.

The plates are then placed over the machine thread of the bolts.

Once the plates are in place, if polyaxial washers and smooth plates were used, polyaxial washers should be placed over the plates “dome up.”

Spacer washers are not to be placed above the spine plates.
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 plates and the desired washers in place, the locking nuts are threaded onto the bolts.
REDUCTION OPTION

Where reduction is deemed necessary, apply locking nuts to stabilizing bolts prior to bolts to be utilized for reduction.

With superior and inferior bolts provisionally tightened, the reduction bolts are then tightened using the fixed handled intermediate tightener or modular intermediate/final tightener.

Prior to tightening the locking nut to reduce the vertebral body, the red, T-handled hex lobe driver must be placed into the hex lobe feature on the top of the reduction bolt to prevent the fixed bolt from advancing into the pedicle.

The fixed handle intermediate tightener or the modular intermediate/final tightener is used to tighten the locking nuts.
Reduction of the vertebral body is shown.

**OPTIONAL BOLT COMPRESSION/DISTRACTION**

Compression or distraction with bolts may be accomplished utilizing the bolt style compressors or distractors with associated instruments in the set. The compressor and distractor can be attached to the intermediate/final tightener shaft, or the bolt alignment guide.

**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.

Set at 80 inch pounds of torque, the T-handle is then rotated clockwise until it clicks and resistance is no longer evident.
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.

A NOTE ON NESTED AND SMOOTH PLATE LOCKING OPTIONS

When nested plates are used, a nested nut must be used as well. Standard locking nuts cannot be used with nested plates.

For nested plates, spacer washers may be used under the plate if desired. However, polyaxial washers should not be used under or over the nested plate.
For both smooth and nested plates, washers are optional. The surgeon may choose to place the plate with no washers.

**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 spine plate, directly into the integral nut of a pedicle or reduction bolt.

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

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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 plate on a pedicle bolt. If additional washers are required, a reduction bolt must be used.
EXPEDIENT PLATES SURGICAL TECHNIQUE

EXPEDIENT OFFSET POLYAXIAL BOLTS WITH SPINE PLATES

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 polyaxial 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.
PLATE INSERTION

Measurement is taken for selection of the appropriately sized plate, and smooth or nested plates are chosen based on surgeon preference.

If desired, the plates may be contoured using a plate bender or flat benders.

The plates are then placed over the machine thread of the polyaxial bolts.

Washers are not used with the polyaxial bolt and plate constructs, as the polyaxial motion is contained in the bolt itself.
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.

Apply locking nuts over bolts.

Locking nuts may also be inserted with the nut inserter and alignment post as shown.
REDUCTION OPTION

Where reduction is deemed necessary, apply locking nuts to stabilize superior and inferior bolts prior to bolts to be utilized for reduction.

With superior and inferior bolts provisionally tightened, the reduction bolts are then tightened.

Prior to tightening the locking nut to reduce the vertebral body, the hex lobe driver must be placed into the hex lobe feature on the top of the polyaxial reduction bolt to prevent the bolt from advancing into the pedicle.
BOLT COMPRESSION/DISTRACTION OPTION

Compression or distraction with polyaxial bolts may be accomplished utilizing the plate compressors or distractors, or rod compressors and distractors.
LOCKING NUT FINAL TIGHTENING

Final tightening is performed with the intermediate/final tightening shaft inserted into the torque wrench, which is set to 80 in-lb of tightening force.

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

The T-handle is then rotated clockwise until it clicks and resistance is no longer evident.
POST CUTTING
If polyaxial reduction bolts were used in the procedure, the posts should be cut with the supplied bolt post cutter.

The post cutter retains the cut post, and by opening the bolt cutter handles the retained piece is dropped out of the base of the cutter.

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

4.35 mm
5.0 mm
6.0 mm
7.0 mm
8.0 mm
9.0 mm

POLYAXIAL BOLTS

POLYAXIAL REDUCTION BOLTS
PLATES

Nested

Smooth

CONSTRAINED SUPERIOR HOLE PLATES

LOCKING NUTS/WASHERS

Locking Nut

Spacer Washer

Polyaxial Washer

Nested Nut for use with Nested Plates
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; curvatures (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 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 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 fatique 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 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 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 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 or 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 loads 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 activities.

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.
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.

DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767
USA
Tel: +1 (800) 227-6633

www.depuy.com

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