

5.5 System

*EXPEDIUM® Spine System
Product Binder*



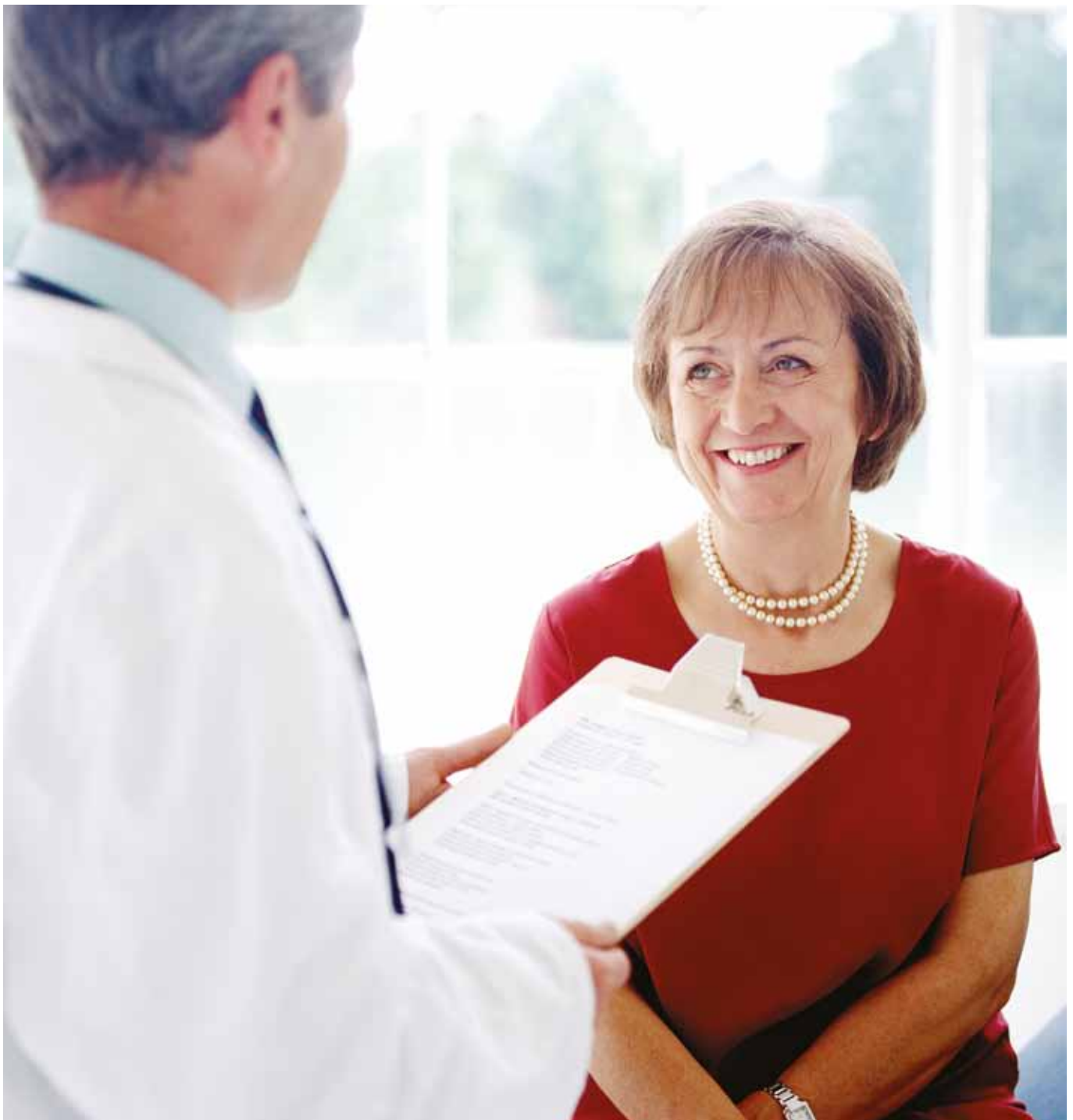
DePuy Synthes

SPINE

Background

The EXPEDIUM Spine System is a feature-rich family of products, providing unmatched confidence in surgical treatment. The EXPEDIUM Spine System platform can be tailored to treat several different spinal pathologies, demonstrating the brand's uncompromising versatility. Through ease of use and innovative design, EXPEDIUM Spine System redefines surgical control for spinal pathologies.

DePuy Synthes Spine has a long tradition of collaborating with experienced spine surgeons resulting in the development of some of the most innovative technologies available today for the treatment of complex spinal pathologies. Years of surgeon evaluation and design input have resulted in the EXPEDIUM Spine System, a comprehensive brand of thoracolumbar spinal products. Characterised by its uncompromising versatility and confidence by design.



Description of System

The EXPEDIUM Spine System is a innovative spine solution with technological advancements that truly differentiate it from other systems available. The EXPEDIUM Spine System is a rod based platform. The system consists of the following:

- Polyaxial Screws (Single Innie, Dual Innie, Favored Angle Screw)
- Monoaxial Screws
- Extended Tab Implants
- Hooks
- Cable and Wires
- EXPEDIUM SFX® Cross Connector System
- EXPEDIUM Universal connector Set
- EXPEDIUM Vertebral Body Derotation
- EXPEDIUM Anterior Spine System
- Sacral Extenders
- Lateral Connectors
- Dual Rod Connectors
- Rod diameter options (4.5 mm, 5.5 mm, 6.35 mm)
- Rod material Options (Titanium, Cobalt Chromium, Stainless Steel and PEEK)
 - 4.5 mm Ti, SS, CoCr
 - 5.5 mm Ti, SS, & CoCr
 - 6.35 mm Ti, & SS

In addition, the system also includes Dual-Innie (DI) Screws, providing Independent Locking Technology, one of the most significant technological advancements since the original Polyaxial Screw and the Favored Angle Screw (FAS). You will find that the EXPEDIUM Spine System provides direct benefits in your hospital for a number of pathologies.

The EXPEDIUM Spine System offers a comprehensive solution for rigid posterior fixation of the thoracolumbar regions of the spine. This unique system combines simplicity and versatility allowing the surgeon to design the construct based on intra-operative developments and individual patient anatomy – not the constraints of the implant system.

The EXPEDIUM Spine System offers significant and unique design innovations, giving you a versatile system with maximum flexibility. These uniquely designed system components include the:

- TOP NOTCH™ Interface
- Dual Lead Thread
- Uni-Planar Screw
- High & Ultra Strength Rods
- Vertebral Body Derotation System
- DI / Independent Locking Technology
- DI Favored Angle Screw
- VIPER® Cortical Fix Fenestrated Screw (VCFFS)

Manufactured from titanium alloy, this system provides the additional benefits of interfacing with other DePuy Synthes Spine thoracolumbar systems such as our Cervical Posterior spine fixation system:

MOUNTAINEER® OCT Spine System, and our Minimally Invasive Spine System: VIPER and VIPER 2 Systems.

Indications

The EXPEDIUM and VIPER/VIPER 2 Spine Systems are intended to provide immobilisation and stabilisation 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 and VIPER/VIPER 2 Spine Systems are 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;
- pseudoarthrosis;
- failed previous fusion in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the VIPER/VIPER 2 Systems are 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, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

*For additional information please refer to the Instructions for Use (0902-90-015)

System Overview

Building upon over 20 years of clinical experience with the MOSS® and MOSS® MIAMI Spinal Systems, the EXPEDIUM Spine System represents a real advance in design technology whilst retaining the benefits of sound surgical philosophy and reliable biomechanical performance.

The EXPEDIUM Spine System features two state-of-the-art internal closure mechanisms.

The comprehensive implant set is designed to work in harmony with the instruments, to maximise intra-operative flexibility and to help meet the challenges of even the most difficult pathologies.

At the forefront of our product we are proud to highlight the system's:

- Design through Experience
- Uncompromising Versatility
- Redefining Control

Design through Experience

The EXPEDIUM Spine System was developed in conjunction with some of the most experienced spine surgeons worldwide. Their experience with pedicle-based anchors has influenced the fundamental design features of the four EXPEDIUM pedicle screw offerings. These optimised features, born from years of experience and clinical use, are present across the feature-rich EXPEDIUM family platform.

Breadth of clinical application

Peer-reviewed literature ranging from individual case studies to prospective case series representing patients treated in Australia, Germany, Greece, and the United States documents clinical experience with the EXPEDIUM Spine System across a broad range of pathologies and procedures.^{1,2,3,4} Patients with degenerative spinal conditions, trauma, and complex spinal deformities are represented. In multiple studies, the EXPEDIUM Spine System was used during complex anterior-posterior column spinal reconstruction procedures.^{2,4}

Examples of some of the unique features and benefits found in the EXPEDIUM Spine System implant offering:

Features	Benefit
Square Thread Closure Mechanism	Minimize head spreading forces and potential cross threading, providing enhanced security and safety.
TOP NOTCH Interface	Secure, in-line instrument attachment which improves accessibility, simplifies maneuvers and enhances intra-operative visualisation.
Self Tapping Double Lead Thread	Operative efficiency- decreasing insertion time when compared single lead thread.
Dual Locking Screw Design	Parallel distraction and compression giving a wide range of possibilities in one screw. The Dual-Innie or DI Screws provide the flexibility of placement of a Polyaxial Screw with the correction capability of a Monoaxial Screw. Consisting of a pre-assembled blue outer ring and centre set screw, this technology allows the surgeon to turn a Polyaxial Screw into a Monoaxial Screw at any desired angle.

References

1. Fracture-related Thoracic Kyphotic Deformity Correction by Single-stage Posterolateral Vertebroectomy with outcomes in 30 Cases; Yoo C, Ryu SI, Park J.; Spinal Disord Tech 2009;22(7):492-501.
2. Minimal Access Versus Open Posterior Lumbar Interbody Fusion in the Treatment of Spondylolisthesis; Ali Ghahreman, Richard D. Ferch, Prashanth J. Rao, Nikolai Bogduk; Neurosurgery Volume 66:296-304, 2010
3. Impact of iliac crest bone graft harvesting on fusion rates and postoperative pain during instrumented posterolateral lumbar fusion; Constantin Schizas, Dimitrios Triantafyllopoulos, Victor Kosmopoulos, Kosmas Stafylas; International Orthopaedics (SICOT) (2009) 33:187-189
4. Pedicle Subtraction Osteotomy; Praveen V. Mummaneni, Sanjay S. Dhalla, Stephen L. Ondra, Valli P. Mummaneni, Sigurd Berven; Neurosurgery 63:A171-A176, 2008

Uncompromising Versatility

Tailored to treat multiple spinal pathologies the breadth of the EXPEDIUM platform demonstrates the brand's Uncompromising Versatility.

The EXPEDIUM family of products exhibits uncompromising versatility in pedicle screw offerings. Each polyaxial screws style offers a set of unique features which, when properly incorporated into the surgical strategy, may reduce intra-operative challenges and maximise surgical efficiency and clinical benefit.

Features	Benefit
Complete product portfolio. Wide range of screw implants such as Monoaxial, SI and DI Polyaxial Screws, Favored Angle Screws (FAS), Uniplanar Screws, Extended Tab Screws, VIPER Cortical Fix Fenestrated Screws, Sacral Extenders, and Various Hook Styles.	Allow for optimal screw placement without compromising control. Implants accommodate patient anatomy and surgeon preference.
Ultra & high strength rods (Stainless Steel) and Cobalt-Chromium Alloy Rods	Designed to maintain correction and provide visualisation.
Compatible with our Posterior Cervical and MIS Spine System platforms (MOUNTAINEER® OCT Spine System and VIPER System)	Linking our various spine systems into one system, running from the occiput to sacrum.



Redefining Control

The EXPEDIUM brand implants have been designed in harmony with the instruments offering security and control during surgery.

The TOP NOTCH Interface, fixed handle probes, silicone handles and intuitive reduction solutions are just a few of the advancements made with the EXPEDIUM Instrumentation.

Features	Benefit
Tapered screw tip and double lead thread form	Self-centres screw trajectory to help ensure accurate and safe placement during insertion of the screw into the pedicle.
Multiple rod reduction instruments	Provide control and power in rod reduction with surgeon preference in mind.
Vertebral body de-rotation instruments	Offering control during corrections and manoeuvres.



EXPEDIUM Screw Overview

Monoaxial Screws

Monoaxial screws have long been used as construct anchors in the lumbar spine. Over the past decade, they have been used with increasing frequency in the thoracic spine particularly at the apex of scoliotic curves. Despite the non-pivoting shank, the Monoaxial screw head offers a lower profile and rigid design which surgeons can use to facilitate vertebral body derotation maneuvers.

Features	Benefit
Rigid Shank	Provides rotational capability for vertebral body derotation maneuvers.
Low Profile Head	Allow placement in high thoracic vertebrae where anatomical clearance is critical.
Single lead thread form	Allow precise adjustment of screw height to maximise head interface with rod.



Uniplanar Screws

The unique Uniplanar screw design is fast becoming the preferred anchoring screw for the use in complex scoliotic deformities. Combining the rod-alignment capabilities of a polyaxial screw with the vertebral body control of a Monoaxial screw. The Uniplanar screw is changing the way surgeons facilitate global correction of complex spinal deformity.

Features	Benefit
Cephalad/Caudal Plane Angulations	Allow for secure mating to the rod despite screw trajectory.
Medial/Lateral Plane Rigidity	Allows for direct vertebral body derotation and control, much like Monoaxial Screws.
Single Lead Thread Form	Allows precise adjustment of screw height to maximise head interface with rod.



VIPER Cortical Fix Fenestrated Screw

The VIPER Cortical Fix Fenestrated Screw is the first pedicle screw implant to offer enhanced fixation in both the pedicle and vertebral body. The cortical fix thread form was designed to provide increased resistance to pull-out by doubling the number of screw/bone contact points. With the additional option to inject cement through the screw shank and into the vertebral body, this implant is key for patients in whom screw purchase is a real concern.

Features	Benefit
Top notch design of screw head	Allows the surgeons to use the system in Open or MIS (EXPEDIUM and VIPER) approaches without the need for additional instrumentation and learning a new technique for screw placement.
Cortical Fix Thread Form (Quad Lead Thread in proximal/cortical section)	Increases fixation by doubling the screw-bone contact interface in the cortical wall of the pedicle.
6 Distal Fenestrations	Allows augmentation of cement around the distal portion of the screw. Positioning of the fenestrations helps to reduce the risk of cement flowing back into the pedicle.
Constant thread lead from dual to quad lead thread	Allows for a smooth transition between the dual lead thread and the quad lead thread forms during insertion.



EXPEDIUM Screw Overview

Single Innie Polyaxial Screws

The Polyaxial screw is considered the “workhorse” of the EXPEDIUM Spine System. Polyaxial screws are used across all levels of the thoracic and lumbar spine, particularly where anatomical constraints dictate the trajectory of the pedicle screw. This trajectory can be achieved using Polyaxial Screws, without sacrificing the ability to align the screw head and rod for final closure.



Specialised Features and Benefits	
<p>60° Cone of Angulation Allows for secure mating of screw head and rod for final closure despite shank trajectory.</p>	
<p>TOP NOTCH Interface Provides secure mating interface with instrumentation for reduction, derotation, and set screw insertion while reducing run on rod and improving visualisation.</p> <p>Allows for in-line anchoring of derotation instruments, thereby providing for secure connection while reducing rib hump.</p>	
<p>Tapered Tip 10 mm distal taper allows screw to self-centre down the pedicle during insertion.</p>	
<p>Square Thread Closure Minimises head spreading forces and potential for cross threading.</p>	
<p>Dual Lead Shank Thread Reduced insertion time when compared to single lead thread.</p>	

EXPEDIUM Screw Overview

Extended Tab Single Innie Polyaxial Screws

Extended Tab Single Innie Polyaxial Screws have long been used as a spondylolisthesis reduction implant in the thoracic and lumbar spine.

The screw offers the feature and benefits of the Single Innie Polyaxial Screws combined with the extended tab design.



Specialised Features and Benefits

Extended Tab Option

Allows for secure mating of screw head and rod for final closure despite shank trajectory.



TOP NOTCH Interface

Provides secure mating interface with instrumentation for reduction, derotation, and set screw insertion while reducing run on rod and improving visualisation.

Allows for in-line anchoring of derotation instruments, thereby providing for secure connection while reducing rib hump.



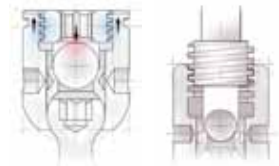
Tapered Tip

10 mm distal taper allows screw to self-centre down the pedicle during insertion.



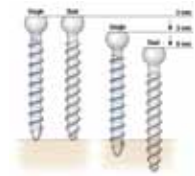
Square Thread Closure

Minimises head spreading forces and potential for cross threading.



Dual Lead Shank Thread

Reduced insertion time when compared to single lead thread.



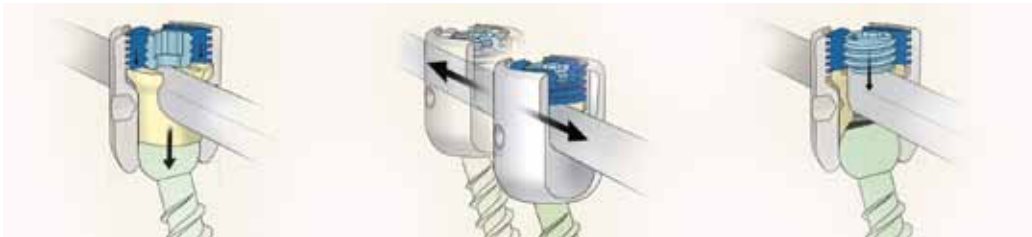
EXPEDIUM Screw Overview

Dual-Innie Polyaxial Screws

One way DePuy Synthes Spine has differentiated our screw systems is the inclusion of Dual Innie Technology, or “independent locking” functionality.

In the simplest terms, Dual-Innie (DI) screws offer the surgeon the ease of placement of a polyaxial screw, with the correction capability of a monoaxial or uni-planar screw.

The following illustrations depict the function of the DI screw:



Tightening of outer ring (blue) locks the poly screw shaft angle, in effect making it a fixed screw.

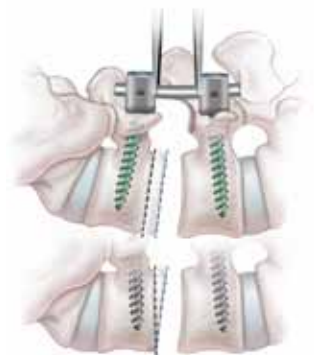
The fixed angle screw moves freely along rod during alignment maneuvers.

Tightening inner set screw head (pink) locks the screw to the rod.

Benefits of Dual Innie Technology

When compressing and distracting, surgeons report a “toggle” effect, whereby the polyaxial capability of the screw allows the head to tip slightly, decreasing the surgeon’s overall control of the correction. Dual Innie screws allow the surgeon to remove “toggle” from the construct by locking the trajectory and spacing on the rod. Additionally, locking the trajectory can allow greater overall distraction in the anterior portion of the disc space, creates parallel distraction, and can improve access for interbody devices.

EXPEDIUM Dual Innie screw, with no “toggle” and increased parallel distraction.



Traditional Poly Screw with reduced distraction due to head “toggle”.

The Dual-Innie Clinical Benefit

Degenerative Surgeon	<ul style="list-style-type: none"> • Parallel distraction, improved disc space access • Improved access to place larger cages/graft • Improved access for placing TLIF cages (Turning the corner) • Improved mechanical advantage when distracting by sharing the load of the distraction across the entire screw • Spondylolisthesis reduction
Trauma Surgeon	<ul style="list-style-type: none"> • Improved fracture reduction with parallel compression
Deformity Surgeon	<ul style="list-style-type: none"> • Improved control over vertebral body with locked screw • Anatomical screw trajectory with the benefit of control • Anchor point control in coronal and sagittal planes

EXPEDIUM Screw Overview

Dual-Innie Favored Angle Screws (FAS)

The EXPEDIUM FAS Screw System is designed to allow for optimal screw fixation and intraoperative flexibility.

The EXPEDIUM FAS screw has been developed by surgeons to bring together the key features of three generations of deformity systems, combining the utility of side loading, mono axial and poly axial implants in one screw. The engineering featured within the screw allow easy and repeated changes of function of the EXPEDIUM FAS screw during the operation with only minimal additional instruments. A powerful flexibility tool allowing the surgeons to use whichever techniques to obtain an optimal result. The experience of decades of differing philosophies has come together in one product.

The dedicated instruments provide a streamlined option for inserting, manipulating and tightening the implants.



Specialised Features and Benefits

Favored Angle

Allows multiple reduction techniques and combines top loading & side loading principles.

Dual Locking Mechanism

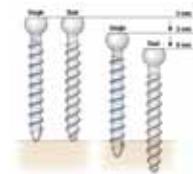
Offering the benefits and flexibility of a polyaxial screw with the correction control of a monoaxial screw

Extended Tab

- Facilitates spreading forces across all anchor points
- Easy capturing of the rod, even if over-contoured.

Dual Lead Shank Thread

Reduced insertion time when compared single lead thread.



Sacral Fixation Options

EXPEDIUM 5.5 Spine System offers specific sacro pelvic implants to allow surgeons to easily extend their construct to the pelvis area. These implants can be used with the standard EXPEDIUM instruments.

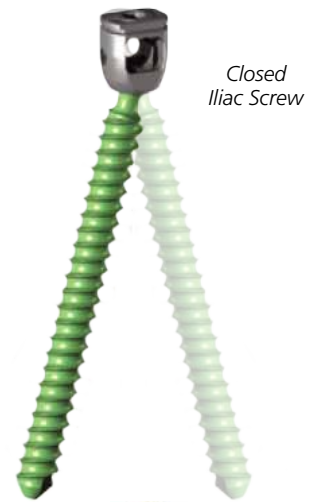
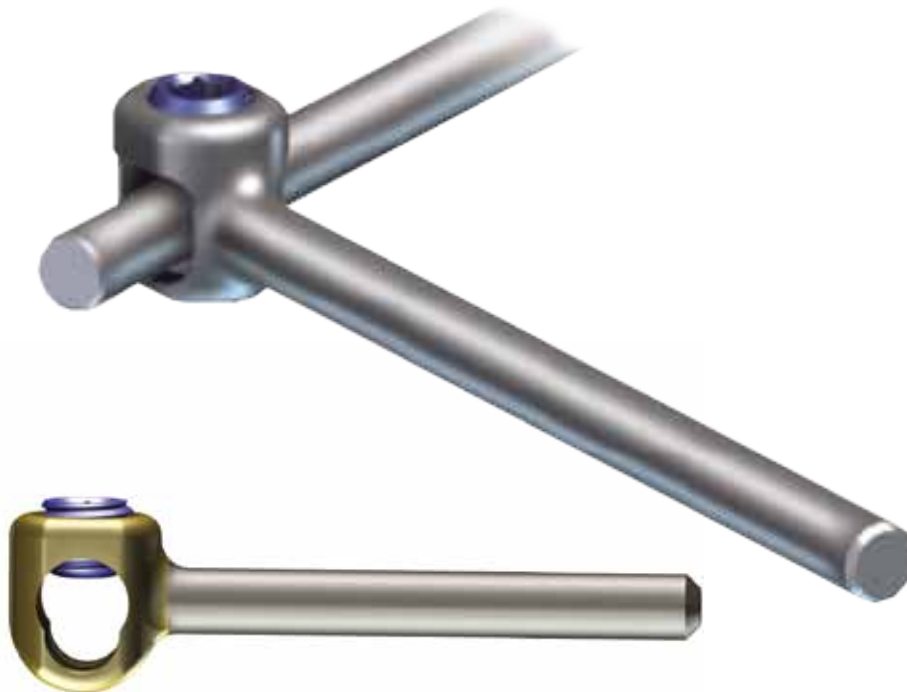
OPEN ILIAC SCREWS: low profile EXPEDIUM polyaxial screws that include also the TOP NOTCH feature for ease of implantation.

CLOSED ILIAC SCREWS that offer the lowest profile in a polyaxial screw and instrumentation for allow for muscle sparing and percutaneous techniques. There is a specific instrument, the Closed Polyaxial Mini Sticks, that has been designed to allow the implantation of this screw with minimal muscle damage or via a mini-open approach.

ILIAC BOLTS that offer the lowest profile anchor option and intra-operative flexibility to accept either a 5.5 or 6.35 rod.

LATERAL CONNECTORS with different configurations for intra-operative flexibility. We supply four types of connectors: Open & Closed, Fixed & Polyaxial.

The EXPEDIUM Sacropelvic Collection adapts to patient anatomy and surgeon's preferred sacropelvic fixation technique. All lateral connectors feature a low profile to minimise tissue disruption in the sacropelvic area. The polyaxial design of the lateral connectors facilitates rod placement and contributes to the efficiency of the procedure.



Closed Iliac Screw



Iliac bolt



Lateral Connectors



EXPEDIUM Hooks

Since the EXPEDIUM Spine System has been developed based on the MOSS MIAMI philosophy, the original hook selection included a variety of hook styles, in one throat depth size.

EXPEDIUM Spine System provides you with a comprehensive range of options to allow for intra-operative flexibility that deformity cases require.

The EXPEDIUM Spine System offers the following hook additions:

- Pedicle Hook
- Wide Blade Hook
- Reduced Distance Hook
- Angled Blade Hook
- Narrow Blade Hook
- Extended Body Hook
- Right/ Left Angled Hook
- Right/ Left Offset Hook
- Side Tight Hook Left/Right
- Ext. Tab Pedicle Hook



Wires

The EXPEDIUM 5.5 spine systems offers Cobalt Chromium wires in the following configurations:

Button Wire – reference 175461000



Double wire – reference 175461005



Single Beaded wire – reference 175461010



The diameter of the wire is 1 mm. The three types of wires are visually distinguished from our stainless steel ones by the black lines along them.

There is a specifically designed instrument kit for the wires.

	P/N	Description
	2797-87-000	Wire Cutter
	2797-87-001	Wire Twisting Forceps
	2797-87-005	EXPEDIUM Wire Retriever
	2797-87-006	EXPEDIUM Wire Retriever with T-Handle
	2797-87-003	EXPEDIUM Small Wire Twister
	2797-87-004	EXPEDIUM Wire Cutter – Small
	2797-87-002	EXPEDIUM Jet Wire Twister

EXPEDIUM Rods

Rod material options (Titanium, Cobalt Chromium, Stainless Steel and PEEK)

- 4.5 mm Ti, SS, CoCr
- 5.5 mm Ti, SS, & CoCr
- 6.35 mm Ti & SS

The EXPEDIUM Spine System components are available in commercially pure titanium or titanium alloy conforming to ASTM F-67 or ASTM F-136 specifications, stainless steel conforming to ASTM F-138, ASTM F-1314, or ASTM F-2229 specifications as well as longitudinal rods in cobalt-chromium-molybdenum alloy conforming to ASTM F-1537, and PEEK polymer.

The EXPEDIUM Cobalt-Chromium Alloy (CoCr) rods were launched as part of DePuy Synthes Spine continuous effort to offer new and exciting options to deformity surgeons. These new rods can be used with the Titanium EXPEDIUM Spinal System and are available in two diameters: 4.5 mm and 5.5 mm.

The introduction of EXPEDIUM Cobalt Chromium Rods provides a solution to surgeons' concerns with the loss of sagittal & coronal alignment during intra-operative deformity correction maneuvers. In addition, they also offer an alternative for cases in which surgeons are forced to choose between having the imaging capabilities offered by Titanium and the mechanical properties offered by Stainless Steel.

Cobalt-Chromium is a metal alloy that has been used in the medical device industry for many years¹. CoCr was chosen for orthopedic implants because of its specific mechanical properties, lower corrosion levels and its compatibility with Ti alloys.

1. Kwak D, Slivka M. *Biomechanical Characterization of Cobalt-Chromium Alloy Spinal Rods*.
White Paper Feb 2009

The main features and benefits of EXPEDIUM CoCr Alloy Rods are listed in the following table:

Features	Benefit
Greater stiffness than Ti and SS rods	Rods are designed to hold their shape during correction maneuvers
Better imaging compatibility than SS	Rods allow for post-operative imaging
Combined with Ti screws show equivalent corrosion properties to SS screw-SS rod construct	Similar or better corrosion resistance than SS screw-rod combination
CoCr is available as part of the 4.5 and 5.5 EXPEDIUM Spine Systems (Ti)	An even more versatile EXPEDIUM Spine System

Patents

GENERALLY Related Product	Patent/Application No.	Title
Polyaxial Screw	US 5,207,678 - expired	Pedicle Screw and Receiver Member Thereof
Favored Angle Polyaxial Screw	US 6,736,820 – exclusive license	Bone Screw
Receiver with Threads Above Rod construct	US 8,123,784 – non-exclusive license	Anchoring element for use in spine or bone surgery, methods for use and production
Bottom Loading Polyaxial Screw	US 6,835,196 – non-exclusive license	Anchoring Element
Receiver with Square Threads	US 2003/0100896 – pending application, non-exclusive license	Element with a shank and a holding element connected to it for connecting to a rod
Uni-planar Screw	US 7,951,172	Constrained Motion Bone Screw Assembly
Clip-On Reduction Instrument	US 7,824,411 and US 7,824,416 and US 7,842,044	Instruments and Methods for Bone Anchor Engagement and Spinal Rod Reduction
Dual Pivot Reduction Instrument	US 7,572,281	Instrument for Guiding a Rod Into an Implant in a Spinal Fixation System
Lateral Reduction Instrument	US 2007/0260261 – pending application	Instruments and Methods for Manipulating a Spinal Fixation Element
One Handed Rod Approximator	US 7,887,541	Spinal Rod Reduction Instruments and Methods for Use
Vertebral Body De-Rotation Instrument	US 7,951,168 and US 7,951,175 and US 8,007,516	Instruments and Methods for Manipulating Vertebra

Registered Trademarks



The EXPEDIUM Spine System
 The EXPEDIUM Anterior Spine System
 The EXPEDIUM Vertebral Body Derotation System
 The EXPEDIUM Feature
 The EXPEDIUM SFX Cross Connector System
 The EXPEDIUM 4.5 System
 The EXPEDIUM 5.5 System
 The EXPEDIUM 6.35 System
 The EXPEDIUM Closed Polyaxial Screws
 The EXPEDIUM Favored Angle Screw
 The EXPEDIUM Screw Removal Set
 The EXPEDIUM Universal Connector Set
 The EXPEDIUM Plates System
 The EXPEDIUM Offset System

Centers of Excellence:

Schulthess Klinik,
 Lengghalde 2,
 CH-8008 Zürich
 Switzerland
 Tel. +41 44 385 71 71,
 Fax +41 44 385 75 07

Hospital La Paz
 Pº de la Castellana, 261
 28046 Madrid
 Spain
 Tel: +34 91 727 70 00

Centre for Spine Surgery and Scoliosis Centre
 Am Kiebitzberg 10
 23730 Neustadt
 Germany
 Tel: +49 4561 54 49 01
 Fax: +49 4561 54 4910

Rikshospitalet
 Ortopdeisk avdeling –
 ryggseksjonen
 Gaustadalleen 20
 N-0027 OSLO
 Norway
 Tel: +47 2307 0000

Royal Orthopaedic Hospital
 Birmingham Children's Hospital
 Bristol Road South
 Northfield
 Birmingham
 B31 2AP
 Tel: +44 121 685 4000

Istituto Ortopedico Galeazzi IRCCS
 Via R. Galeazzi 4
 20161 Milano
 Italy
 Tel: +39 02 662141

L'Azienda Ospedaliera
 Via Zuretti 29
 10126 Torino
 Italy
 Tel: +39 11.6933.111



Clinical Papers

Biomechanical Characterization of Cobalt-Chromium Alloy Spinal Rods (DF17-69-002) (Sep-11)

S. Daniel Kwak, PhD, Michael Slivka, MSc and Robert Sommerich, MSc

Abstract: DePuy Synthes Spine is now offering Cobalt-Chromium Alloy Rods (CoCrMo: ASTM F1537) for use in spinal deformity surgery. Cobalt-chromium alloy metals have a long history in orthopedic prosthetics, such as hip and knee replacements, and more recently in spinal applications, such as disc arthroplasty.

Value Analysis Brief - EXPEDIUM Favored Angle Screw (DS03-04-001)

This value analysis brief presents information on the potential benefits of favored angle reduction screws with dual innie technology (FA Screws) relative to standard monoaxial, polyaxial, and uniplanar screws.

Value Analysis Tool – Cobalt-Chromium Alloy Rods (DS03-03-001)

This Value Analysis Tool presents information on the benefits of cobalt-chromium (CoCr) alloy rods relative to titanium (Ti) and stainless steel (SS) rods. The referenced data were obtained through a search of MEDLINE for all peer-reviewed studies published prior to September 2010 on material selection for implants used in spine fusion.

EXPEDIUM Favored Angle Screws in the Degenerative Population (Cat. No. DF17-62-000) (Jan-09)

Kennedy Yalamanchili, MD, FACS

Abstract: EXPEDIUM Favored Angle Screws have a known application in the deformity population, but recently have been noted to have application in the degenerative population, as well. The screw retains a favored angle to permit exaggerated flexibility of the head along its favored angle (approximately 50 degrees)

Kyphosis Correction and Posterior Spinal Fusion Using Titanium EXPEDIUM Favored Angle Screws and CoCr Alloy Rods (Cat. No. DF17-71-000) (Jan-10)

Shay Bess, MD

Abstract: In this case example, the titanium EXPEDIUM Favored Angle Screws combined with CoCr Alloy rods facilitated correction of a large, rigid, spinal deformity. The extended tabs on the pedicle screws facilitated rod capture and allowed gradual reduction of the under contoured rod protecting the pedicle screws from backing out during cantilever deformity correction.

More Options in Scoliosis Patients with the Dual Innie Favored Angle Reduction Tab Screw (DI FAR Screw) (Sep-09)

Florian Geiger

Abstract: In the past, the deformity was only corrected in one plane by means of distraction of the concavity and compression of the convexity (Harrington system), and later the apical translation technique was developed (e.g. Luque wires). After it was discovered that rotation is one of the major problems in this deformity, efforts were made to also restore the sagittal profile by means of rod derotation.

Posterior Spinal Fusion with the EXPEDIUM Cobalt-Chromium Alloy Rods Case Study (Cat. No. DF17-61 000) (Mar-09)

Harry Shufflebarger, MD

Abstract: The EXPEDIUM 5.5 Cobalt-Chromium Alloy Rods provided excellent correction in this example, without loss of the sagittal plane bend (well illustrated on the lateral radiograph). The Cobalt-Chromium rod combined with Titanium Screws permitted adequate visualisation of the spinal canal to rule out intra-canal pathology in the event of neurological complications with the surgical procedure.

Additional Information

Item	Reference
EXPEDIUM 5.5 Sales Sheet	9085-41-000
EXPEDIUM Family Packet	9085-43-000
EXPEDIUM 5.5 Technical Monograph	9085-44-000
EXPEDIUM 5.5 Surgical Technique	9086-77-000
EXPEDIUM Pedicle Screw Insertion Technique	9086-96-000
EXPEDIUM Family Product Catalogue	9083-11-000
Value Analysis Brief- EXPEDIUM CoCr Rods	9087-30-100
VIPER Cortical Fix Fenestrated Screw Surgical Technique and Product Catalogue	9085-38-000



Ref: 9085-44-000



Ref: 9085-43-000

Appendix

Appendix 1

Pitch: The distance between threads. The relative importance of this feature is that the pitch controls the distance the screw thread advances with each revolution.

Dual Lead Thread: Two threads that start and run 180 degrees apart from one another. The EXPEDIUM Polyaxial and DI screws offer this feature to reduce insertion time without compromising screw pullout strength.

Overall Head Height: Less is better as it minimises complications with soft tissue coverage and screw prominence through the skin. Overall Head Height = Height Above Rod + Rod Diameter + Height Below Rod.

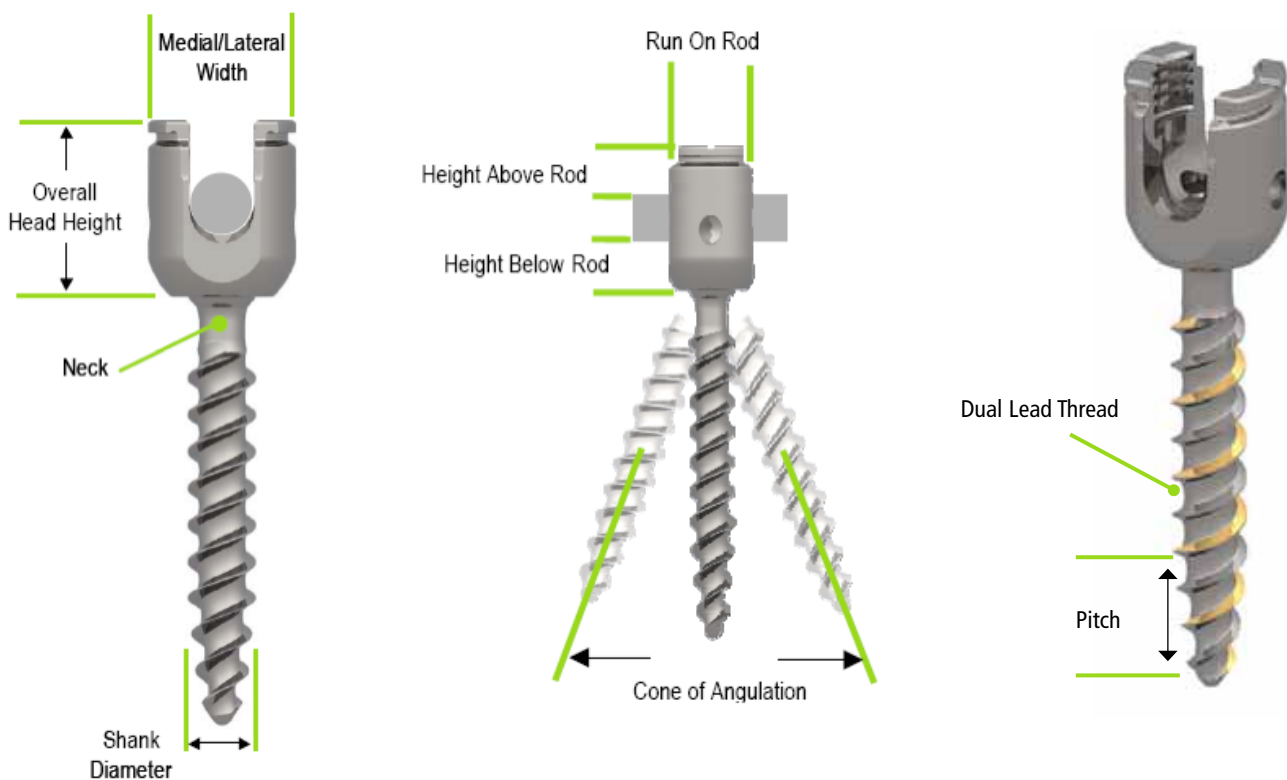
Medial/Lateral Width: This is simply the width of the screw head from the medial to lateral borders. This feature is particularly important as the smaller the width, the less the screw interferes with the spinous process and transverse process.

Run-on-Rod: This dimension is a measure of the cephalad/caudal depth of the screw head, and dictates how closely two adjacent screw can be placed. This is particularly important in the lumbar spine where lordosis brings the screw heads towards each other. Simply put, less run-on-rod is better.

Thread Profile: The thread profile is the specific geometry of the thread. This value in combination with pitch, screw shank diameter, thread height, and screw length dictate the screw pullout strength.

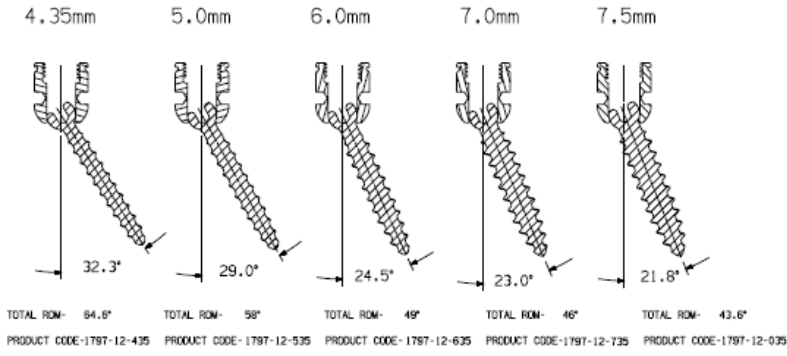
Cone of Angulation: This is the "cone" in which the screw shank can angulate or pivot. Think of this as the angle at which the surgeon can set the trajectory of the screw. More is better as it allows for easy connection of the screw head to the rod. The neck diameter limits the cone of angulation.

Thread Height: Thread Height=Major Diameter – Minor Diameter, and is an indication of the "purchasing" ability of a screw.

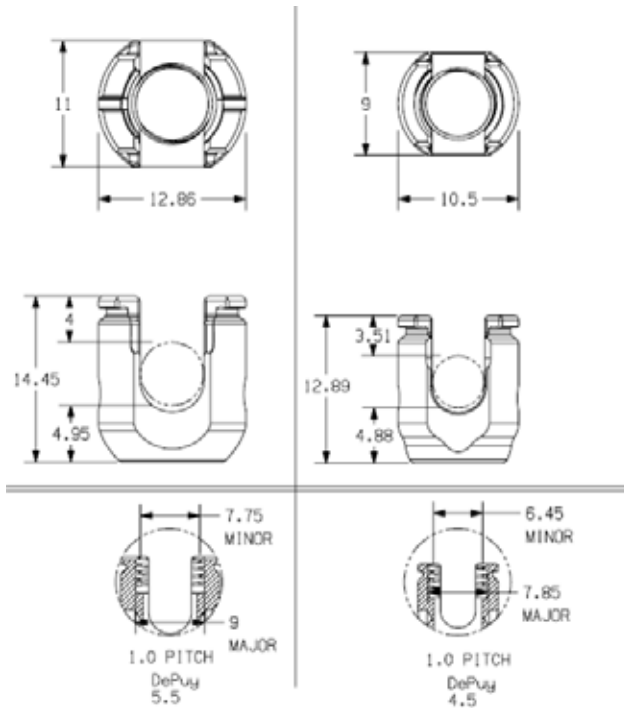
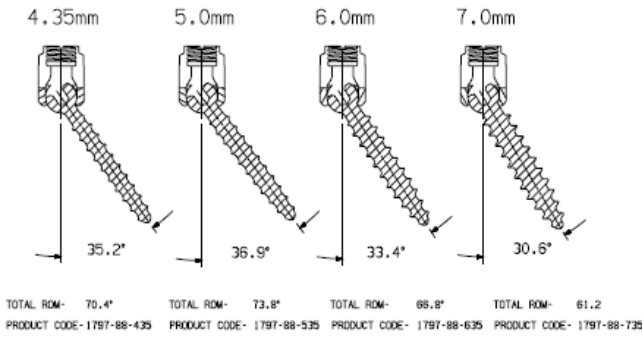


Appendix 2

5.5
POLYAXIAL
SCREW



5.5
UNIPLANAR
SCREW





Indications

The EXPEDIUM and VIPER/VIPER 2 Spine Systems are intended to provide immobilisation and stabilisation 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 and VIPER/VIPER 2 Spine Systems are 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;
- pseudoarthrosis;
- failed previous fusion in skeletally mature patients.

When used in a posterior percutaneous approach with MIS instrumentation, the VIPER/VIPER 2 Systems are 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, pseudoarthrosis; and failed previous fusion in skeletally mature patients.

Limited Warranty and Disclaimer: DePuy Synthes 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.

*For additional information please refer to the Instructions for Use (0902-90-015)

Not for distribution in the USA.

DePuy Spine EMEA is a trading division of DePuy International Limited.
Registered Office: St. Anthony's Road, Leeds LS11 8DT, England
Registered in England No. 3319712

Manufactured by one of the following:

DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767-0350
USA

Medos International SÀRL
Chemin Blanc 38
CH-2400 Le Locle
Switzerland



*For recognised manufacturer, refer to product label.

Distributed in the USA by:

DePuy Spine, Inc.
325 Paramount Drive
Raynham, MA 02767
USA
Tel: +1 (800) 227 6633
Fax: +1 (800) 446 0234

Authorised European Representative:

DePuy International Ltd
St Anthony's Road
Leeds LS11 8DT
England
Tel: +44 (0)113 387 7800
Fax: +44 (0)113 387 7890

www.depuy.com

© DePuy Spine, Inc. 2012.
All rights reserved.

9086-12-403 version 1 08/12
CA8066
CA8621



DePuy Synthes

SPINE

COMPANIES OF *Johnson & Johnson*