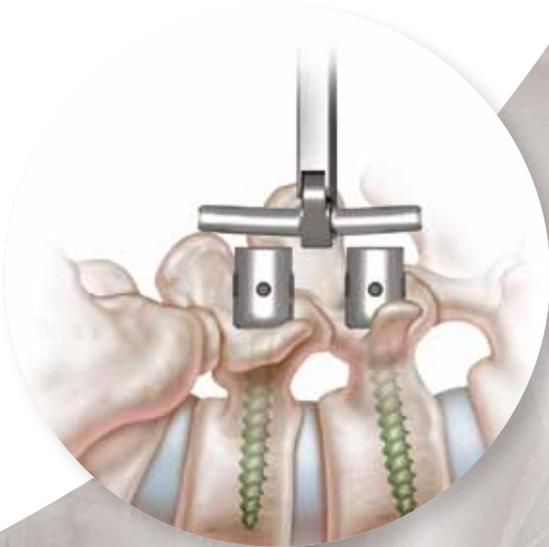




5.5 System

Surgical Technique

Guide



never stop moving[®]





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INTRODUCTION/PHILOSOPHY

Building upon decades of cumulative design history, sound surgical philosophy, clinical experience and biomechanical performance of the MOSS®, MOSS MIAMI™ and MOSS MIAMI™ SI Systems, the EXPEDIUM® Spine System represents a true advance in the treatment of thoracolumbar pathologies.

The EXPEDIUM Spine System incorporates technique-simplifying designs, including a state of the art internal closure mechanism and a comprehensive set of implants designed in harmony with the instruments, which maximise performance and meet the challenge of even the most difficult pathologies.



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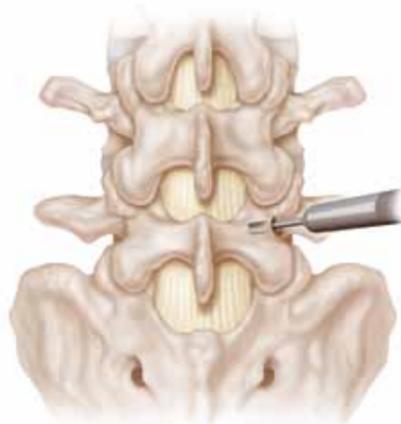
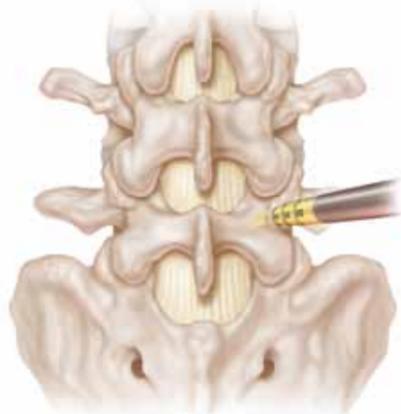
5.5 System

EXPEDIUM POLYAXIAL SCREW

Pedicle Screw Preparation

Pedicle preparation is performed utilising a selection of Awls, Pedicle Probes, Ball Tip Feelers and Bone Taps.

Probes and Bone Taps are marked to indicate the appropriate length Polyaxial Screw.



Polyaxial Screws have a fully threaded, tapered tip minimising the need to tap. However, taps are provided for surgeon preference.

POLYAXIAL SCREWDRIVER APPLICATION

Step 1

Place the tip of the Polyaxial Screwdriver into the head of the screw.



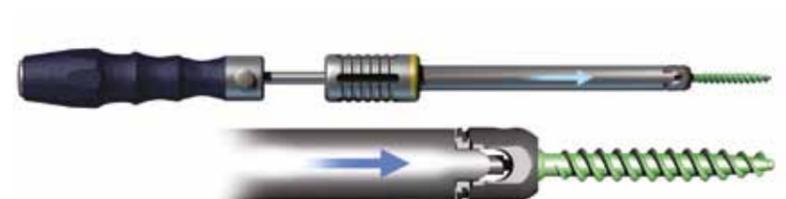
Step 2

Thread the Screwdriver into the head of the screw, making sure the screw shank is straight.



Step 3

Slide the Screwdriver sleeve down into the head of the screw.



Step 4

To adjust the screw height, rotate the outer sleeve counter-clockwise.



Step 5

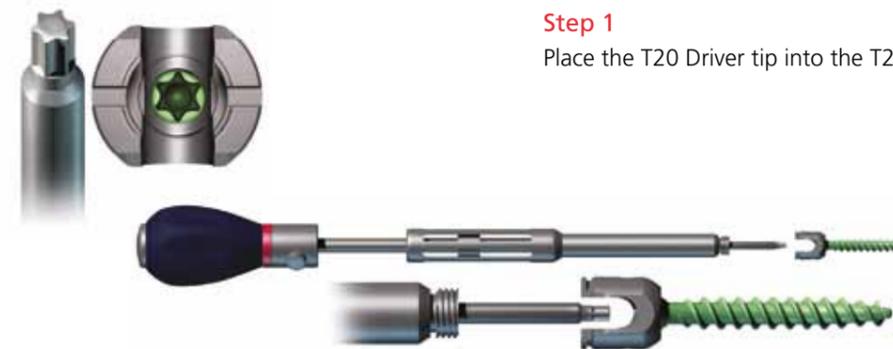
To disengage, retract the Screwdriver sleeve and unthread the driver from the head of the screw.



QUICK-CONNECT SCREWDRIVER APPLICATION

Step 1

Place the T20 Driver tip into the T20 feature in the screw shank.



Step 2

Slide the Screwdriver sleeve down and thread into the head of the screw.



Step 3

To adjust the screw height, rotate the handle counter-clockwise.



Step 4

To disengage the screw, unthread the Screwdriver sleeve.

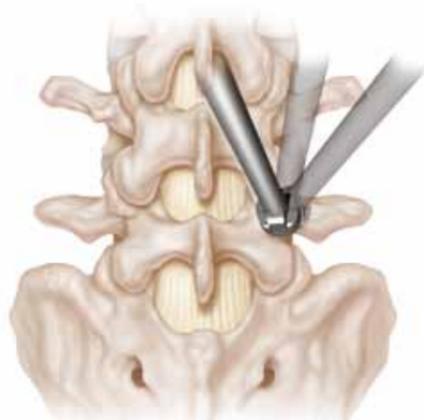


5.5 System

POLYAXIAL SCREW INSERTION

Polyaxial Screws are inserted using the Polyaxial Screwdriver.

NOTE: Note: See Polyaxial Screwdriver application (Page 4)



The Polyaxial Screw head can be adjusted and positioned using the Head Adjuster.



MONOAXIAL SCREWS

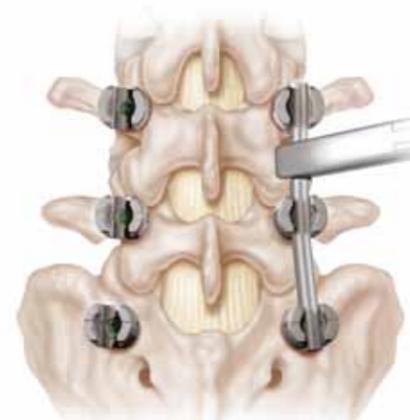


HEAD ADJUSTER

- Monoaxial Screws may be used according to surgeon preference.

ROD INSERTION

Choose the appropriate length rod with the desired lordosis. Place the rod into the Polyaxial Screw heads.

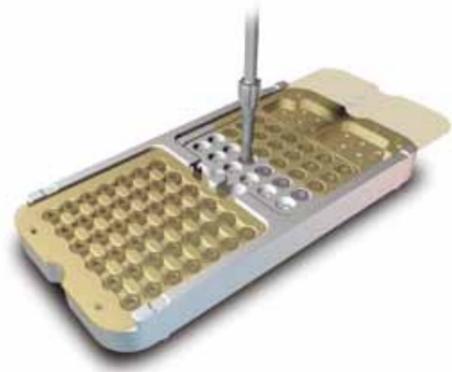


5.5 System

SINGLE INNIE INSERTIONS

Using the Single Innie Inserter, pick up an Innie from the caddy.

The Single Innie will self-retain on the inserter.



Align with the screw head.

Thread into the screw head to capture the rod.

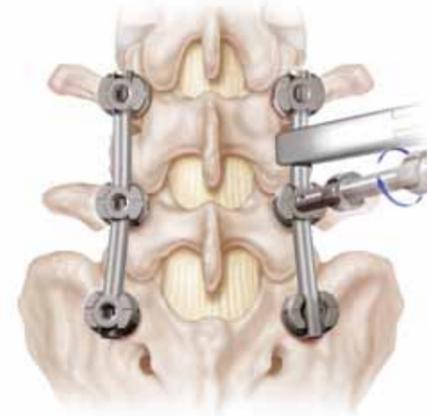


ALIGNMENT GUIDE

ROD CAPTURE

Capture the rod into the implant by inserting the Single Innie.

The Alignment Guide can be used to help position the head and reduce the chance of cross-threading (see page 9).



5.5 System

ROD REDUCTION – CLIP-ON ROD APPROXIMATOR

Attach the Clip-On Device to the TOP NOTCH™ feature at the top of the Polyaxial Screw head.



Load the Single Innie from the caddy onto the combination Reduction Tube/SI Inserter.



Thread the Reduction Tube into the Clip-On Device to fully seat the rod.



Capture the rod by threading the Single Innie into the implant head until tight. Remove the Reduction Tube and Clip-On Device.



5.5 System

ROD REDUCTION USING THE SQUEEZE-DOWN ROD APPROXIMATOR



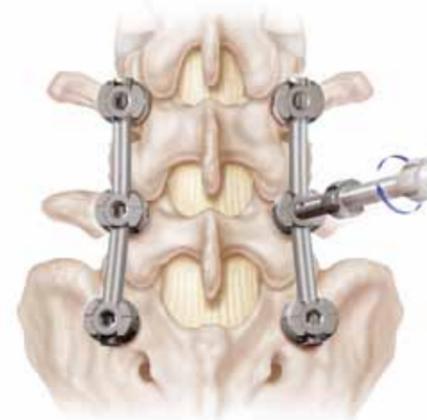
Attach the Squeeze-Down Device to the TOP NOTCH feature at the top of the Polyaxial Screw head.

Fully seat the rod by squeezing the handles together.

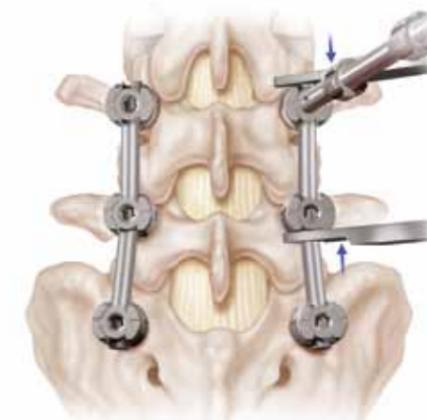
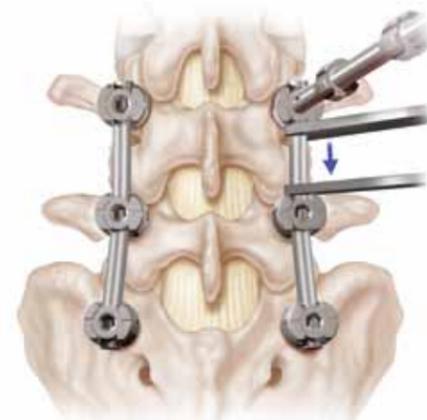


Load the Single Innie from the caddy and thread into the implant head through the guide in the Squeeze-Down Device. Disengage the device from the TOP NOTCH feature.

COMPRESSION/DISTRACTION



Once the rod has been captured into all of the Polyaxial Screw heads, Compression and Distraction maneuvers can be easily accomplished by simply loosening and tightening the Single Innie.



5.5 System

FINAL TIGHTENING

Final tightening is performed with the Hexlobe Shaft inserted into the T-Handle Torque Wrench, set to 9 Nm (80 in-lb).

The shaft is inserted through the Rod Stabiliser and into the Single Innie.

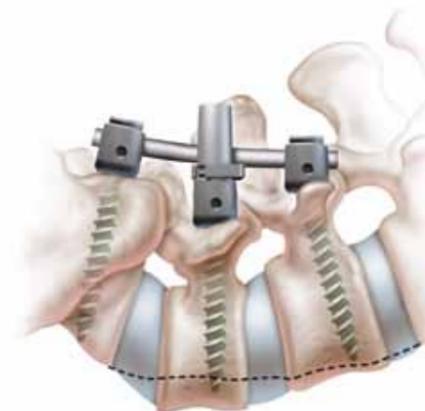
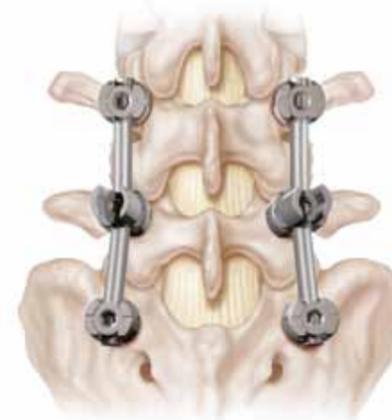
The Stabiliser is then slid down over the head of the Polyaxial Screw and onto the rod. The Stabiliser handle can be held either perpendicular or parallel to the rod. The T-Handle is rotated clockwise until it clicks and resistance is no longer evident.



T-HANDLE TORQUE WRENCH

- T-Handle Torque Wrench set to 9 Nm (80 in-lb).

EXPEDIUM REDUCTION SCREWS



Reduction

The EXPEDIUM Polyaxial Reduction Screw is designed to further complement the innovative design of the existing EXPEDIUM Polyaxial Screw range. These screws help to address, correct and also stabilise difficult anatomic variations. The Reduction Screw is designed with removable tabs that allow the surgeon to approximate the spine to the desired sagittal or axial profile.

Tab Keys or Rings are placed on the extended implant flanges to prevent distortion during rod introduction.



TAB KEY



TAB KEY PLACEMENT



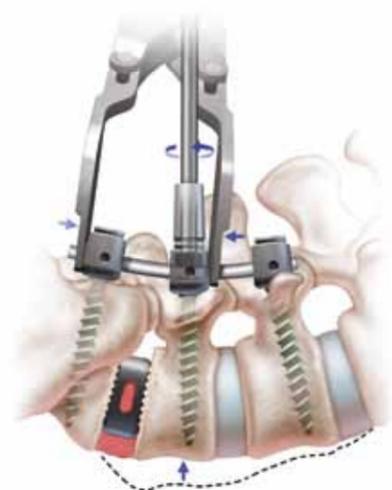
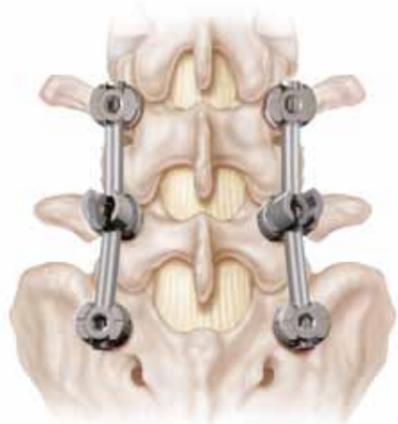
TAB RING



TAB RING PLACEMENT

5.5 System

Following the corrective reduction maneuvers, a Structural Interbody Fusion Device may be inserted via a PLIF or TLIF procedure, if required.



After insertion of the Structural Interbody Fusion Device, Compression and final tightening of the Polyaxial Screws is performed. After final tightening, Extended Tabs may be removed using the Extended Tab Remover (see side panel).



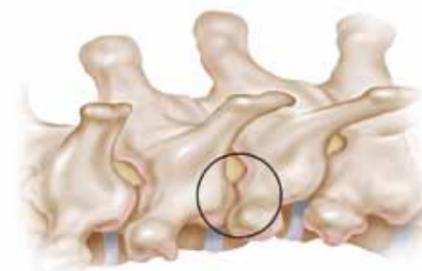
TAB REMOVER

EXPEDIUM HOOKS

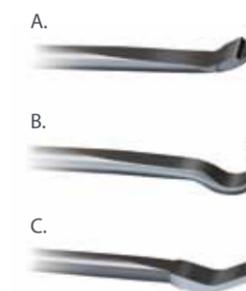
There are four possible hook placement sites in the spine: pedicle, transverse process, supra-lamina and infra-lamina.

The first site is the pedicle. Pedicle Hooks are placed in the thoracic spine via the facet joint. The direction for the Pedicle Hooks is always cephalad.

The facet of the appropriate level is identified and the capsule is removed. The cartilage on the inferior articular process of the next distal level should be visualised.



The facet is entered with the Pedicle Elevator.



HOOK PREPARATION INSTRUMENTS

- A. Thoracic Facet Finder
- B. Laminar Finder
- C. Pedicle Finder



The Pedicle Hook is inserted with either the Compact Hook Holder or the Hook Holding Forceps and seated flush against the facet and the pedicle.

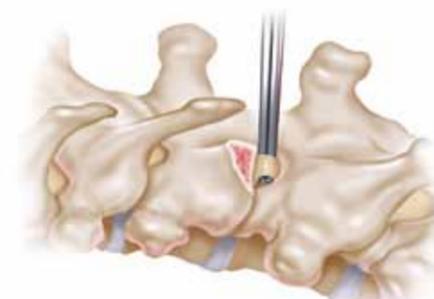


The second site is the transverse process. This is usually used in conjunction with a Pedicle Hook either at the same level or one level superior. A Wide Blade Lamina Hook or Angled Body Lamina Hook is recommended for this site.

An Elevator is used to dissect around the superior surface of the transverse process.



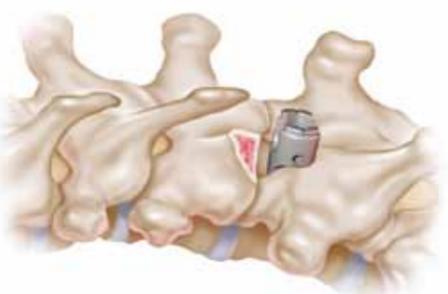
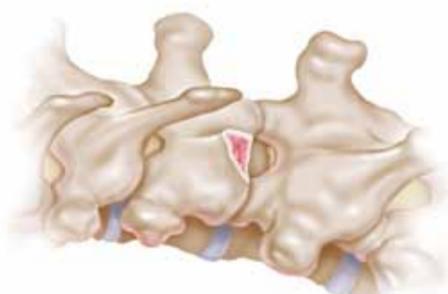
The Wide Blade Lamina Hook or Angled Body Lamina Hook is then placed in the required position.



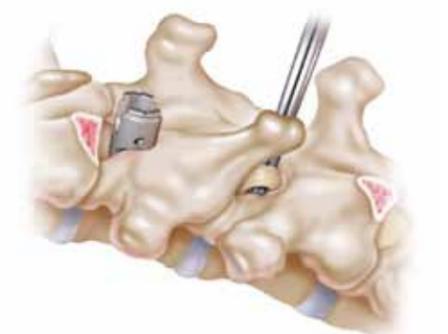
The third possible site is the superior lamina. The Reduced Distance Lamina Hook or the Narrow Blade Lamina Hook is recommended for this site. The direction is always caudal. These hooks may be combined with other hooks to produce a claw construct.

The ligamentum flavum is divided in the midline and excised.

The inferior edge of the next proximal lamina is removed to permit the intra- canal placement of the hook.



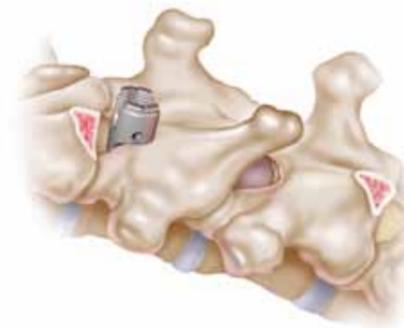
The appropriate lamina hook is then placed using the Hook Holding Forceps until well seated against the lamina.



The fourth possible site is the inferior lamina. The Angled Blade Hook is recommended for this site in the lumbar spine. The direction is always cephalad.

Similar to the Supra-Lamina Hooks, the ligamentum flavum is divided in the midline and excised.

The inferior edge of the selected lamina is removed to permit intra-canal placement of the hook.

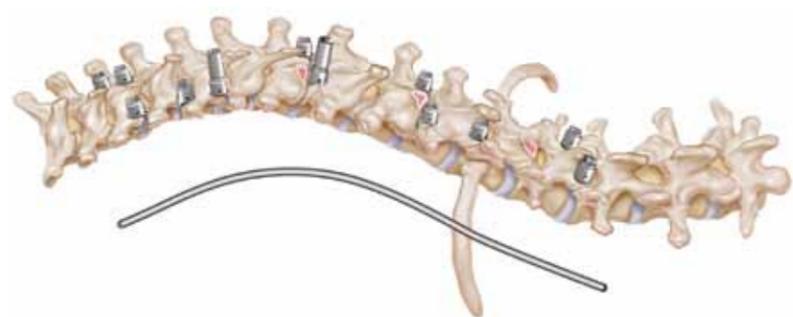


The Angled Blade Lamina Hook is then placed using the Hook Holding Forceps until well seated against the lamina.

EXPEDIUM TRANSLATION HOOKS

The EXPEDIUM Translation Hook is designed to further complement the innovative design of the existing EXPEDIUM hook range. These hooks help to address, correct and also stabilise difficult anatomic variations. The Translation Hook is designed with removable tabs that allow the surgeon to approximate the spine to the desired sagittal or axial profile.

Translation Hooks are most commonly placed at the apex of the concavity. Contour the rod to match the required spinal contours in the sagittal plane.

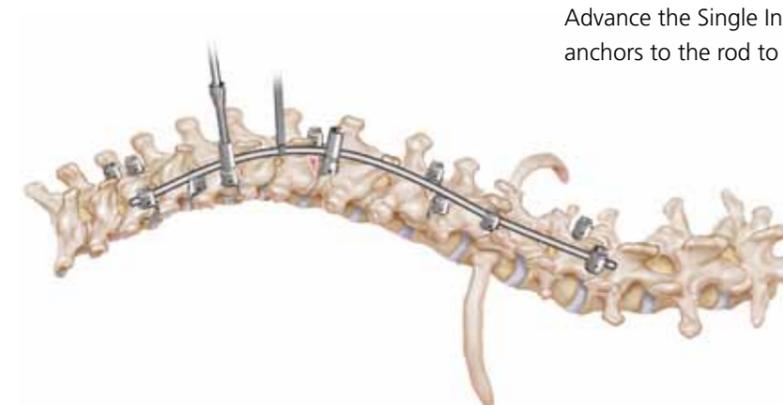


Place the contoured rod into the spine anchors. Fully seat and secure the rod by introducing the Single Innie. The extended tabs of the Translation Hooks provide a means of capturing a rod that may have crossed the midline and would otherwise be out of reach of the anchor.



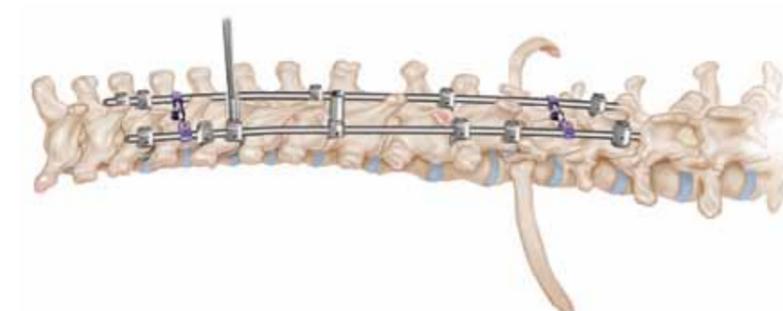
Distraction is applied as the rod is translated into the hooks using the Single Innie.

Note: Minimal distraction between Translation Hooks should be utilised during translation to prevent hook dislodgement.

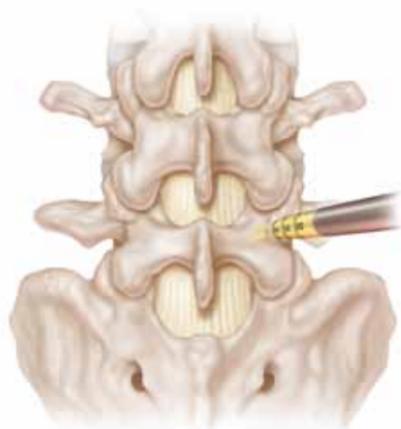


Advance the Single Innie within the flanged hook to bring the spinal anchors to the rod to correct the scoliosis.

Once the rod is fully seated, the Approximation Tabs can be removed using the Tab Remover. Additionally, Cross Connectors can be used to add structural rigidity to the construct.



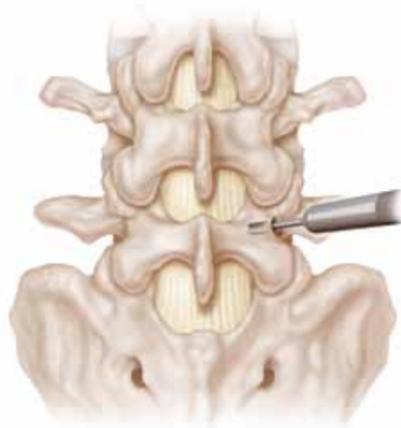
EXPEDIUM DUAL INNIE POLYAXIAL SCREWS



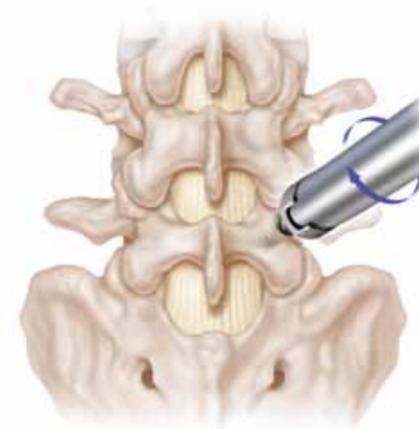
Pedicle Screw Preparation

Pedicle preparation is performed utilising a selection of Awls, Pedicle Probes, Ball Tip Feelers and Bone Taps.

Probes and Bone Taps are marked to indicate the appropriate length for Polyaxial Screw selection.



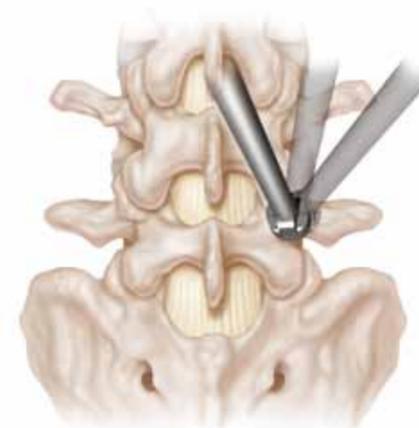
Polyaxial Screws have a fully threaded, tapered tip minimising the need to tap. However, taps are provided for surgeon preference.



Polyaxial Screw Insertion

Polyaxial Screws are inserted using the DI Polyaxial Screwdriver.

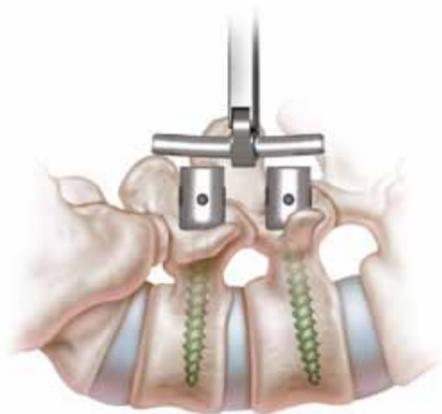
Note: Polyaxial Screwdriver application is similar to the method described earlier (Page 4).



The Polyaxial Screw head can be adjusted and positioned using the Head Adjuster.

Rod Insertion

Choose the appropriate length rod with the desired lordosis. Place the rod into the Polyaxial Screw heads.



Dual Innie Insertions

Using the Dual Innie Inserter, pick up a Dual Innie Set Screw from the caddy. The Dual Innie will self-retain on the inserter.



Align with the screw head.

The Alignment Guide can be used to help position the head and reduce the chance of cross-threading (see page 9).

Thread into the screw head to capture the rod.

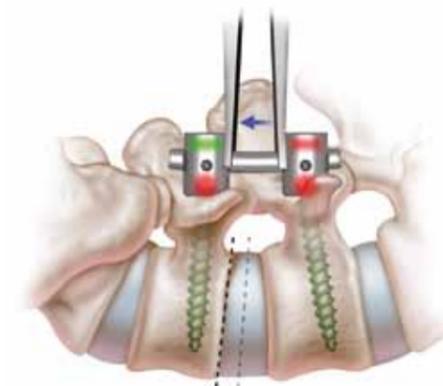


5.5 System

TLIF/PLIF USING EXPEDIUM DUAL INNIE POLYAXIAL SCREWS



Screw shank angulation can be locked by tightening the outer blue set screw of the closure mechanism using the Cannulated T-Handle Intermediate Tightener. The X-25 Hexlobe Driver should be used to center the Intermediate Tightener.



Distraction along the entire vertebral body is achieved when the polyaxial mechanism is locked for all screws.



Secure the rod to the proximal screw on each side of the spine by tightening the inner set screw with the X-25 Hexlobe Driver.

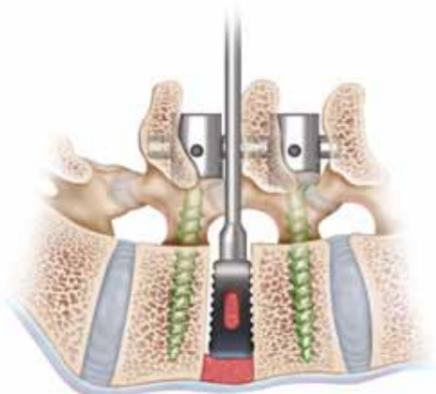


Distraction is held by locking the remaining inner set screws with the X-25 Hexlobe Driver.

With the distracted disc space temporarily held open, the intervertebral disc can be safely removed.



Placement of Structural Interbody Fusion Device can be checked visually and, if appropriate, radiologically.



Parallel compressive forces can be applied to secure the Structural Interbody Fusion Device. Simply loosen the appropriate inner setscrew and tighten after compression is accomplished.

Note: The polyaxial mechanism can be released by loosening the blue outer setscrew to ensure good apposition between the implant and the adjacent endplates.



FINAL TIGHTENING



Final tightening of the outer set screw is performed with the Dual Innie Tightener.

The shaft is inserted through the Rod Stabiliser and into the outer set screw.

The Stabiliser is then slid down over the head of the Polyaxial Screw and onto the rod. The Stabiliser handle can be held either perpendicular or parallel to the rod.

The T-Handle is rotated clockwise until tight.



Final tightening of the inner set screw is performed with the Hexlobe Shaft inserted into the T-Handle Torque Wrench, set to 9 Nm (80 in-lb).

The shaft is inserted through the Rod Stabiliser and into the internal set screw.

The Stabiliser is then slid down over the head of the Polyaxial Screw and onto the rod. The Stabiliser handle can be held either perpendicular or parallel to the rod.

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



T-HANDLE TORQUE WRENCH

- T-Handle Torque Wrench set to 9 Nm (80 in-lb).

INDICATIONS:

The EXPEDIUM® Spine System is 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® Spine System metallic components are intended for noncervical pedicle fixation and nonpedicle fixation for fusion 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); tumour, pseudoarthrosis; and failed previous fusion in skeletally mature patients. The EXPEDIUM® PEEK rods are only indicated for fusion procedures for spinal stenosis with instability (no greater than Grade I spondylolisthesis) from L1-S1 in skeletally mature patients.

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.

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