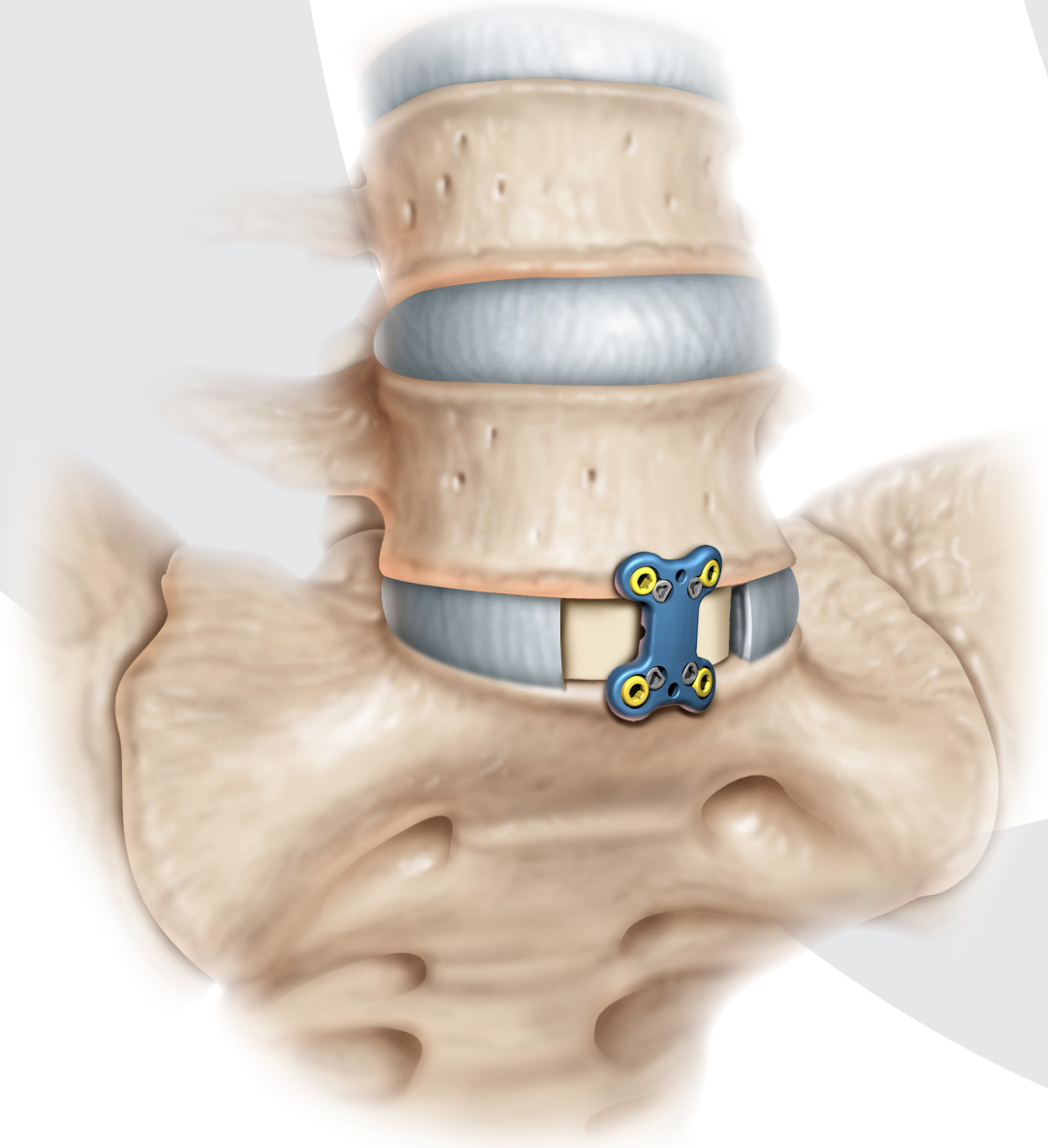
AEGIS® Anterior Lumbar Plate System

Surgical Technique



DePuy Synthes

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Contents

MR Information
This device has not been evaluated for safety and compatibility in the MR environment.
This device has not been tested for heating or migration in the MR environment.

Product Overview

Introduction

The AEGIS® Anterior Lumbar Plate System is designed to provide anterior stabilization to the lumbar spine through the use of a contoured, low-profile plate. In cases where anterior stabilization is indicated, the use of the AEGIS Anterior Lumbar Plate, together with the insertion of structural allograft or an interbody fusion device, provides biomechanical stability while fusion is achieved.

System Description

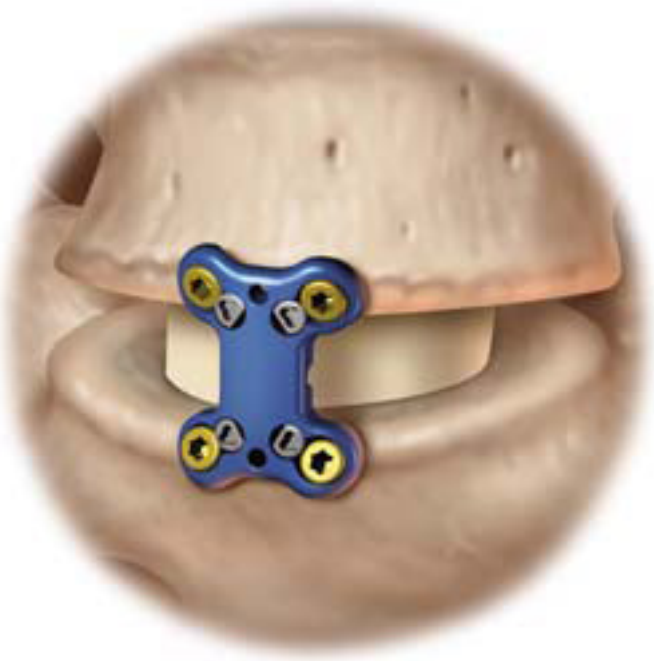
The following are key features of the AEGIS Anterior Lumbar Plate System:

Plate Design

- Low profile anterior intra-discal orientation
- Variable angle (15°) screw placement
- Cortical rim screw fixation
- Tri-Lobe CAM-LOC™ screw locking mechanism

Instrumentation

- Lateral and midline plate holders
- Integrated variable and fixed awl and drill guides
- Self-retaining screw driver
- Plate trials for templating and sizing



Operative Technique

General Considerations

The anterior lumbar and lumbosacral spine may be accessed through an extra-peritoneal approach. The supine position is favored for the lower lumbar segments for more optimal restoration of lumbar lordosis and for more optimal visualization of the posterior annulus, posterior longitudinal ligament, and spinal canal. Coordination with a vascular or general surgeon trained as a spinal access surgeon is recommended.

Step 1

Target Level Preparation and Approach

Determination of approach to the anterior lumbar spine is dependent on the level or levels to be fused. Evaluation of lumbar radiographs and/or MRI/CT helps determine the anatomic relationships between the highest and lowest interspaces approached, the superior iliac crest, lordotic angles, sacral inclination, and position of the blood vessels.In general, topographical landmarks for strategic incision placement include:

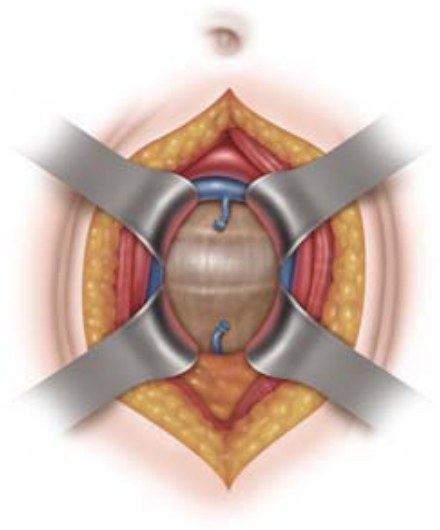
- L3-L4, the level of the umbilicus,
- L4-L5, the level of the intercrestal line,
- L5-S1, the level midway between the umbilicus and the symphysis pubis.

For two level exposure, the incision may be placed midway between the appropriate levels. For more than two sequential operative levels, a left para-median vertical incision is more advantageous.

Approach of L5-S1

Direct anterior placement of the AEGIS Anterior Lumbar Plate is appropriate at the L5-S1 disc level if the bifurcation of the great vessels is above this level.

Fig. 1

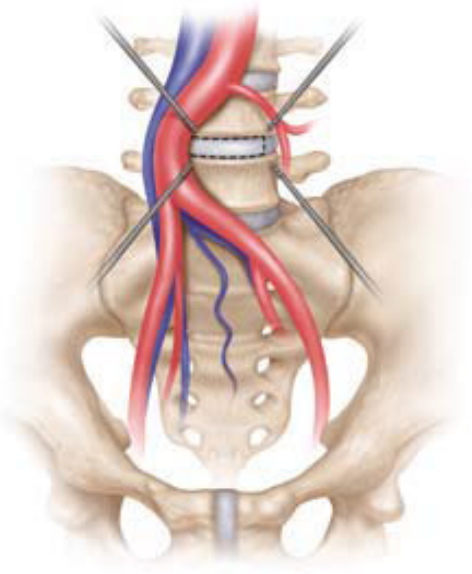


L5-S1

Approach of L4-L5 and above

Above L5-S1, careful mobilization and retraction of the common iliac vein or veins beyond midline is necessary for adequate exposure to the anterior or anterolateral aspects of the spine.

Fig. 2



L4-L5

Step 2

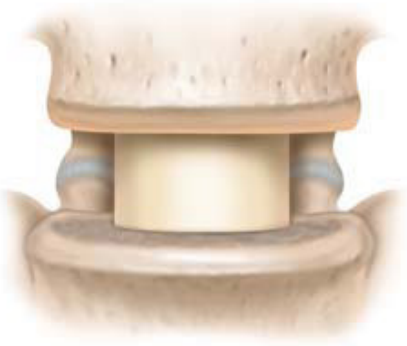
Anterior Decompression and Discectomy

For optimal AEGIS Plate application, impeding anterior osteophytes on the surface of the vertebral bodies should carefully be debrided.

Precaution: **Aggressive osteophyte debridement may potentially weaken the integrity of the superior and inferior anterior vertebral body cortical rims. Intact cortical rim structure is important for optimal plate positioning and optimal screw purchase.**

After the insertion of an interbody spacer such as VG1® ALIF Allograft or a DePuy Synthes interbody fusion device, ensure that the spacer is adequately recessed in the disc space.

Fig. 3

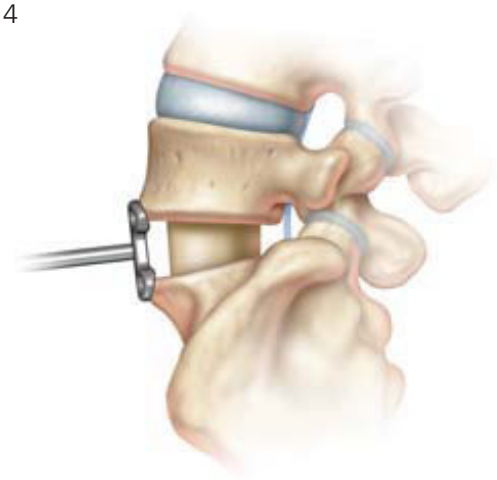


Step 3

Plate Selection

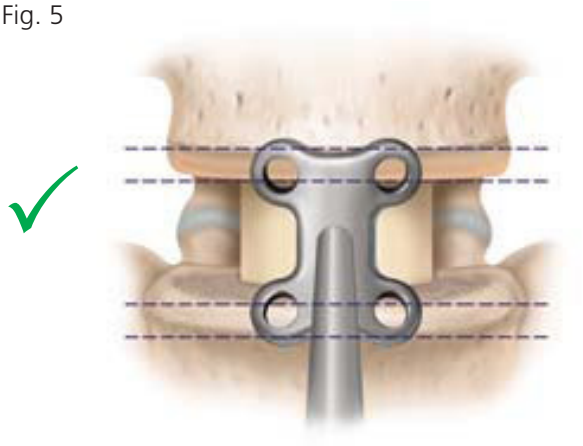
Single-level AEGIS Plates are available in lengths from 15 mm to 25 mm. Plate trials may be used to directly select the appropriate plate size. During pre-operative measurements from radiographs, and with intra-operative templating with plate trials, **the plate screw holes should not extend past the respective cortical rims. When fitted properly, the screw holes should be more than half filled with cortical rim bone minimizing any breach of the endplate**. Proper fitting will allow the plate to nest somewhat in the disc space decreasing the prominence of the plate. Proper fitting will encourage stable plate/bone interface contact, and promote optimal screw position and fixation.

Fig. 4



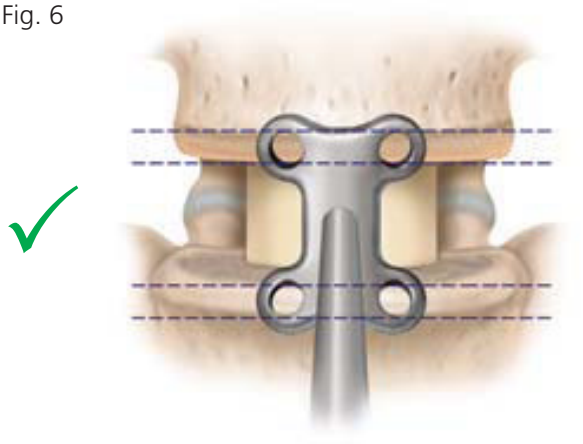
Proper Trial Position

Fig. 5



Optimal Position

Fig. 6



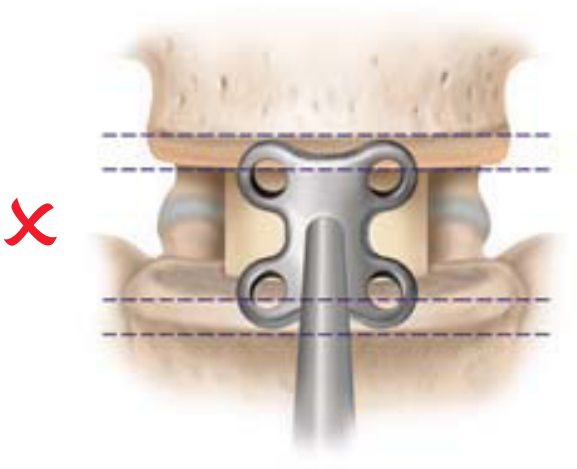
Optimal Position

Step 3

Plate Selection continued

Precaution: Undersizing of the plate may result in sub-optimal screw-to-bone purchase.

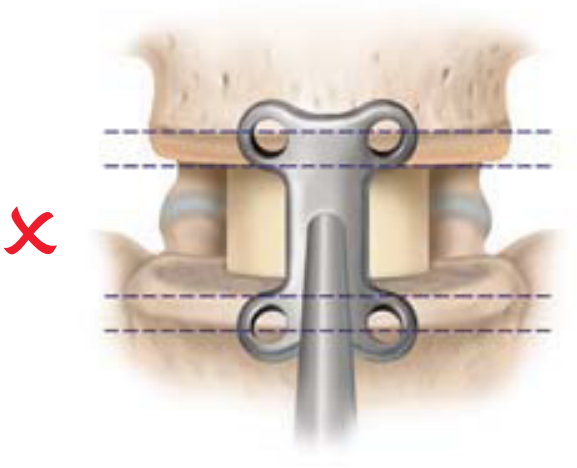
Fig. 7



Undersized

Precaution: Oversizing of the plate may result in potentially increased surface profile.

Fig. 8



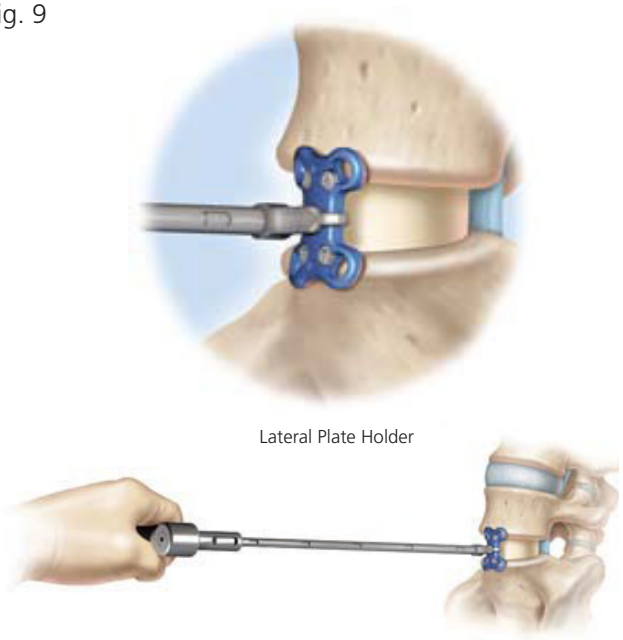
Oversized

Step 4

Plate Application

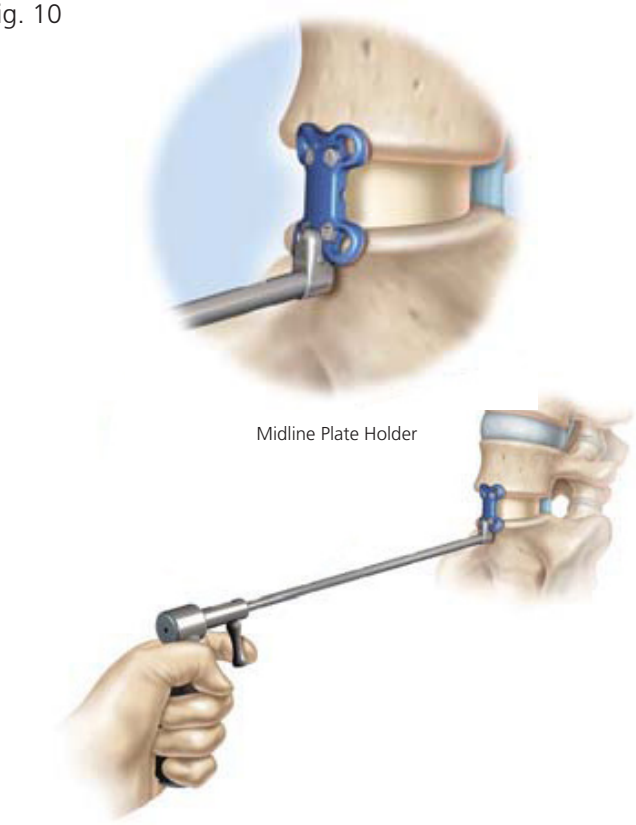
Selection of the midline or lateral plate holder is dependent on anatomy and surgeon preference.

Fig. 9



Lateral Plate Holder

Fig. 10



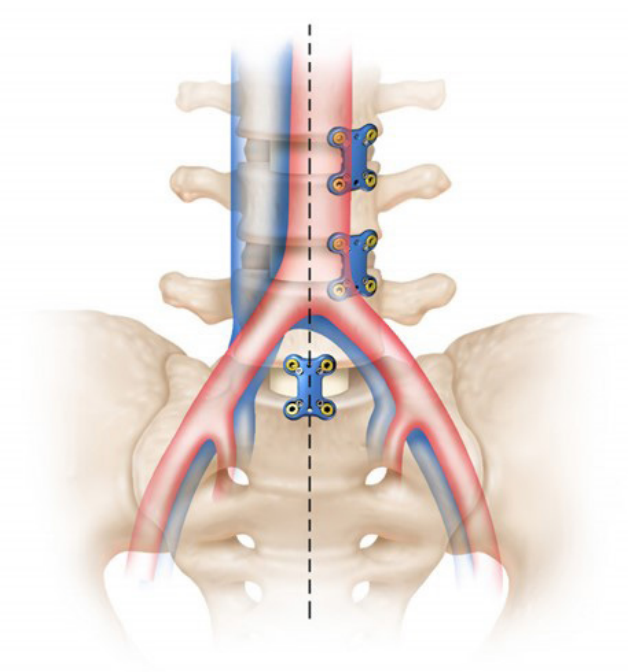
Midline Plate Holder

Step 4

Plate Application continued

Anterior midline or anterolateral positioning of the plate may be dictated by spinal anatomy. At L5-S1, the plate may be applied anterior or directly midline, below the level of the bifurcation of the vessels. At L4-L5 and above the bifurcation, the plate should be placed in an anterolateral or lateral position. The plate should be placed over the window created in the annulus, whether it is directly anterior or anterolateral.

Fig. 11

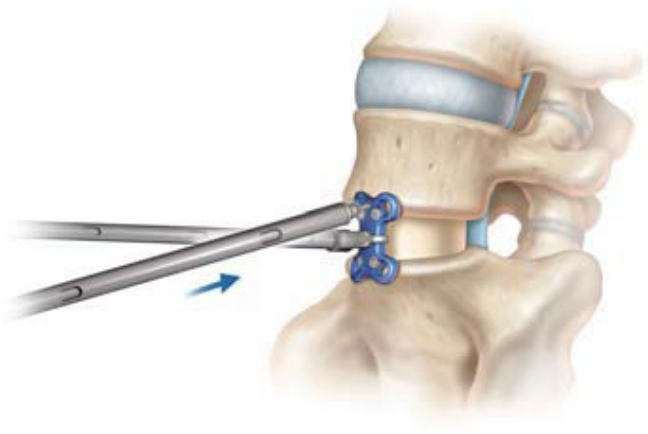


Step 4

Plate Application continued

The plate may be provisionally secured with temporary fixation pins inserted with the temporary fixation pin inserter. When inserting temporary fixation pins, the midline plate holder must be removed prior to placement of the inferior temporary fixation pin. When using the lateral plate holder both temporary fixation pins can be inserted without removing the lateral plate holder.

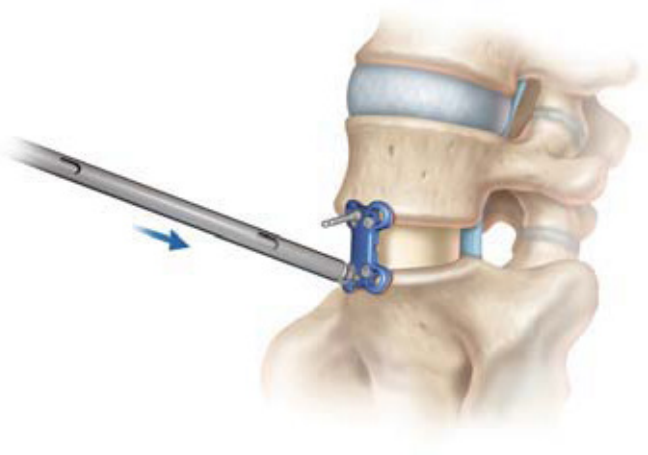
Fig. 12



Upper Fixation Pin

Note: **Once inserted, the fixation pin angle matches the fixed sagittal screw trajectory angle and can be used as a guide when preparing screw holes. Fluoroscopic imaging may be used to evaluate pin angle.**

Fig. 13



Lower Fixation Pin

Step 5

Screw Hole Preparation

Using the Variable Angle or Fixed Angle Awl

The AEGIS Anterior Lumbar Plate System allows for fixed angle or variable angle screw placement. The fixed angle awl creates a screw trajectory that is perpendicular to the 15 degree plate tab in the sagittal plane and 10 degree convergent in the axial plane. Certain anatomy may dictate the use of the variable angle awl to achieve appropriate screw placement. The variable angle awl allows for screw hole placement up to about a 15 degree cone.

To evenly seat and nest the plate it is recommended the screw holes be prepared separately using the awl, drill and tap as needed. The awl may be used to its maximum depth of 20 mm to facilitate insertion of the screws.

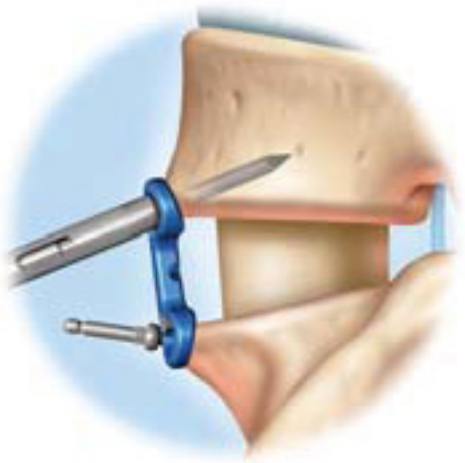
Formal drilling and tapping of the hole is not necessary, as the screws are self-tapping. However, corresponding variable and fixed angle drills are provided in the system. **A diagonal sequence of preparation and insertion may obtain optimal purchase to the bone (i.e. opposite corners)**.

Final tightening should not occur until all four screws have been inserted.

In addition, a depth gauge and 5.2 mm tap with depth markings for the screw lengths can be used to continue screw hole preparation and measurement.

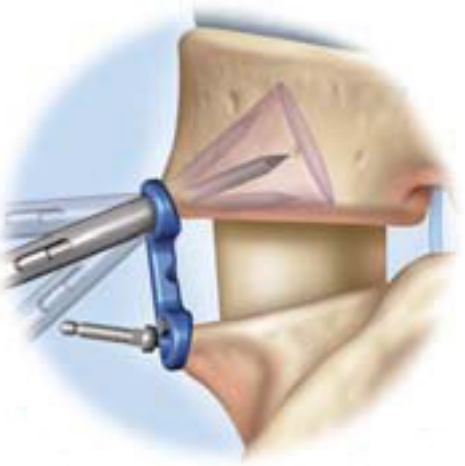
Precaution: **Use caution when using tap at extreme angles as damage to the plate screw hole may occur.**

Fig. 14



Fixed-Angle Awl

Fig. 15



Variable-Angle Awl

Fig. 16

Step 6

Screw Insertion

The AEGIS System offers 5.2 mm diameter self-tapping screws color coded for lengths of 21, 24, 28, 32 and 36 mm. Desired screw length may be determined from preoperative templating.

It is suggested that the screw tips be within 5 to 10 mm of the posterior cortex. The measurements of the screws correspond to the measure of engagement into the bone.

Precaution: **If both 36 mm length screws are used, screw tips may converge and interfere with each other. Two options to minimize this condition are to 1) use a shorter screw length on one side or 2) use of the variable angled instruments to alter trajectory of the screw.**

Fig. 17

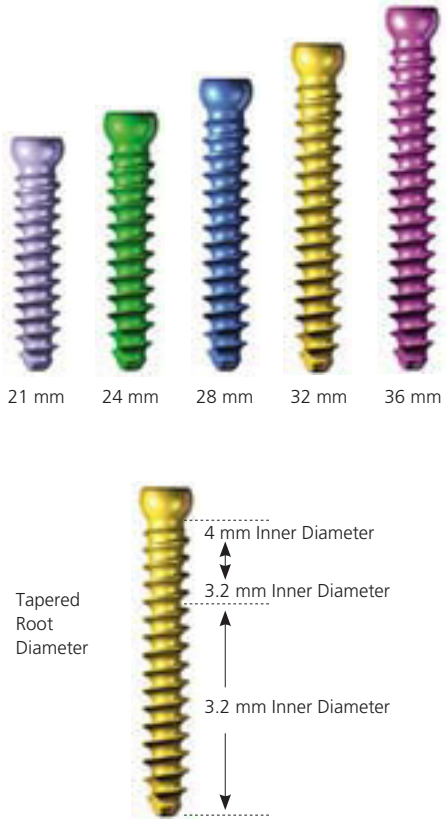
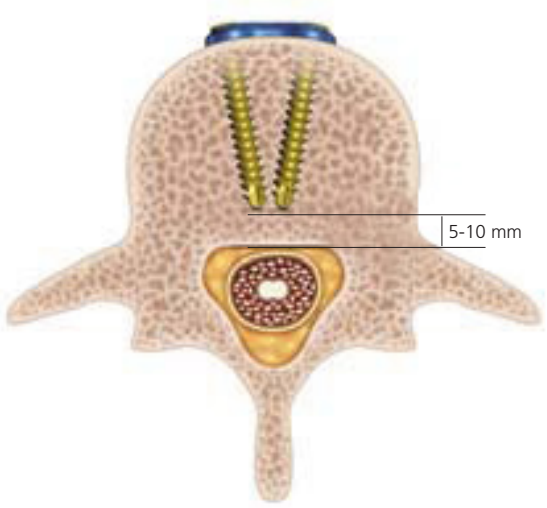


Fig. 18



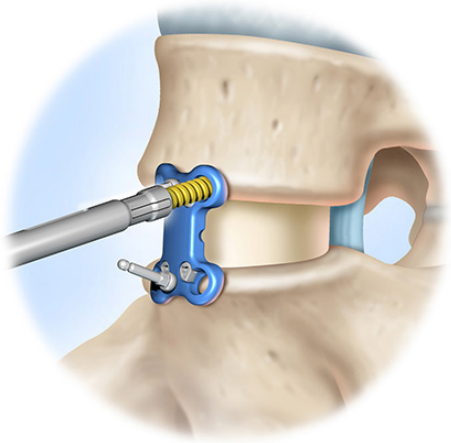
Step 6

Screw Insertion continued

The tapered modular screwdriver and self-retaining driver sleeve (optional) are used to insert the screw.

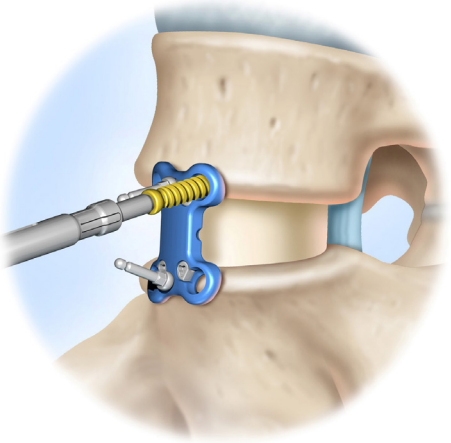
The temporary fixation pins may be removed after the screws are provisionally tightened.

Fig. 19a



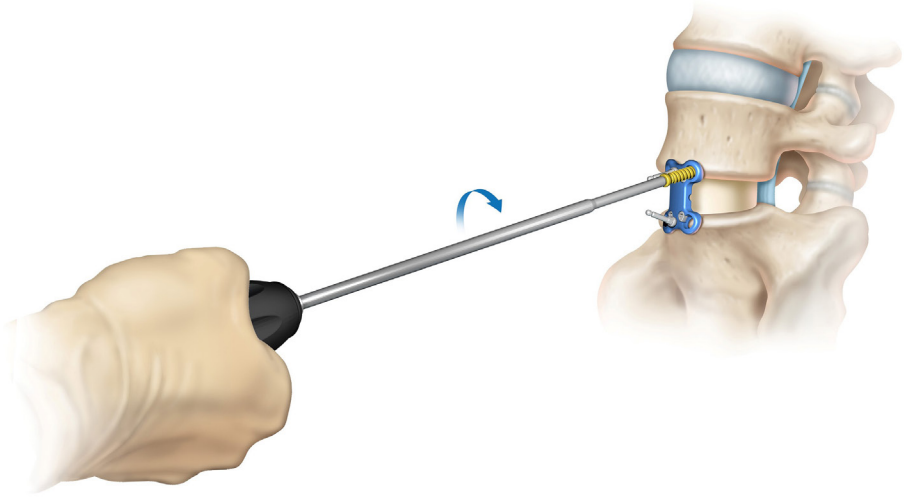
Sleeve Engaged

Fig. 19b



Sleeve Retracted

Fig. 20



Step 7

Final Tightening

Proceed with final tightening of the screws and lagging of the plate.

Fluoroscopic imaging may be used to evaluate screw position, trajectory and length, and should be used to confirm the plate and screw position.

Fig. 21

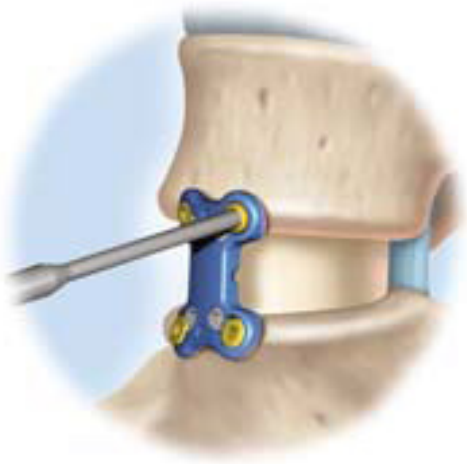
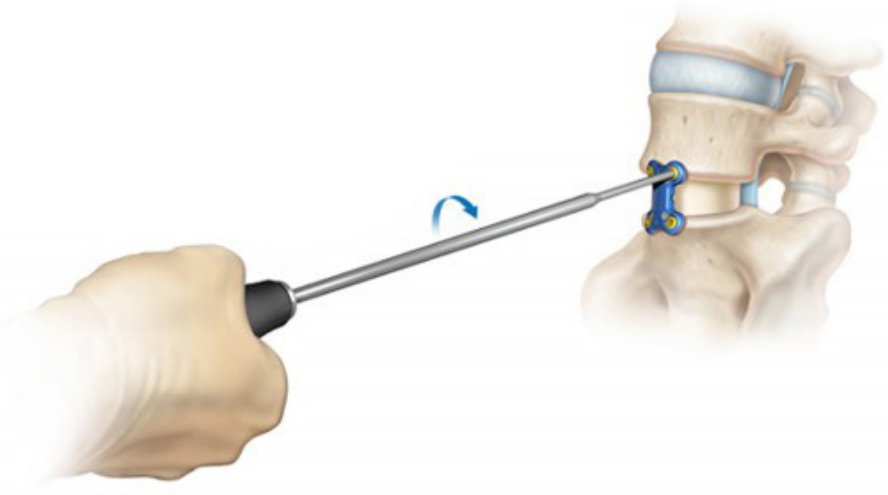


Fig. 22



Step 8

CAM-LOC Mechanism

All screws should be secured to the vertebral bodies before beginning the cam locking procedure.

Assemble the CAM tightener shaft to the torque handle. Note that the shaft is double-ended to provide an additional tip should a tip become worn. **Inspect and ensure tip of the cam driver is free of any damage before using**. Insert the tip of the cam tightener shaft into the cam and ensure that the driver is fully seated within the cam. The flat sides of the cam shaft provide a visual aid when seating the driver shaft into the cam.

Rotate the cam tightener clockwise. Resistance will be felt as the cam contacts the head of the screw. **The cam tightener handle incorporates a torque-limiting (1.5 Nm) feature that will snap out with an audible click ensuring that the cam is properly locked**.

Fig. 23

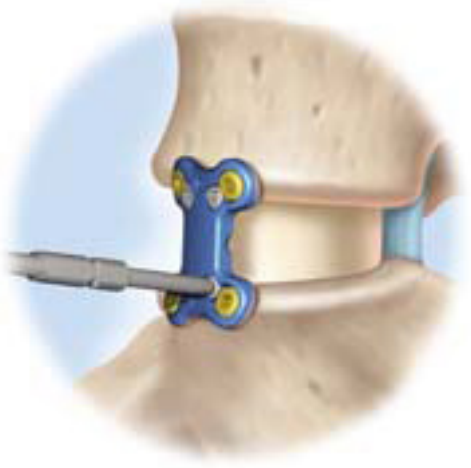
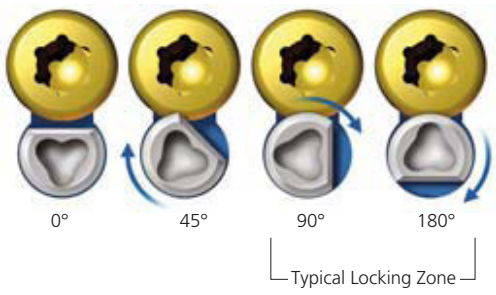


Fig. 24 Rotate the Cam Tightener Clockwise

Note: **Exact position of a locked cam may vary within the typical locking zone depending on screw angulations.**



Ordering Information

AEGIS Anterior Lumbar Plate System

Part Number	Description
Implants	**Plates**
1871-50-015	Anterior Lumbar Plate, 15mm
1871-50-017	Anterior Lumbar Plate, 17mm
1871-50-019	Anterior Lumbar Plate, 19mm
1871-50-021	Anterior Lumbar Plate, 21mm
1871-50-023	Anterior Lumbar Plate, 23mm
1871-50-025	Anterior Lumbar Plate, 25mm
Screws	
1871-55-021	Screw, 5.2mm x 21mm
1871-55-024	Screw, 5.2mm x 24mm
1871-55-028	Screw, 5.2mm x 28mm
1871-55-032	Screw, 5.2mm x 32mm
1871-55-036	Screw, 5.2mm x 36mm
Instruments	
2797-03-140	Ratcheting Elliptical Handle (Optional)
2871-10-100	Awl, Variable
2871-10-110	Drill, Variable
2871-10-115	Awl, Fixed
2871-10-120	5.2mm Tap
2871-10-130	Drill, Fixed
2871-10-140	Fixation Pin-Non Threaded
2871-10-145	Fixation Pin-Threaded
2871-10-150	Fixation Pin Inserter
2871-10-160	Plate Holder Midline
2871-10-170	Plate Holder Lateral
2871-10-190	Cam Tightener Shaft
2871-10-200	Trial, 15mm/17mm
2871-10-300	Trial, 19mm/21mm
2871-10-400	Trial, 23mm/25mm
2871-10-550	Tapered Modular Screw Driver
2871-10-560	Self-Retaining Driver Sleeve (Optional)
2871-10-600	Depth Gauge
2871-10-700	Modular Handle
2871-10-800	Cam Tightener Torque Handle
2871-20-100	Case & Tray
2871-20-200	Plate Caddy (space for Fixation Pins)
2871-20-300	Screw Caddy
2877-10-430	Anterior Ball-Tipped Feeler Probe (Optional)

Indications and Contraindications

Indications

The AEGIS Anterior Lumbar Plate System is indicated for use as an anteriorly placed supplemental fixation device via the lateral or anterolateral surgical approach above the bifurcation of the great vessels, or via the anterior surgical approach below the bifurcation of the great vessels.

The device is intended as a temporary fixation device until fusion is achieved. The AEGIS Anterior Lumbar Plate System is intended for anterior lumbar (L1-S1) fixation for the following indications: degenerative disc disease (DDD) (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), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Contraindications

The following conditions are contraindicated for the AEGIS Plate: extensive calcification of the great vessels, retroperitoneal fibrosis, high-grade spondylolisthesis, tumor or trauma necessitating multiple vertebral segment stabilization.

Additionally, active systemic infection or infection localized to the site of the proposed implantation are contraindications to implantation.

Severe osteoporosis may prevent adequate fixation of the spinal anchors and thus preclude the use of this or any other temporary internal fixation implant.

Any entities or conditions that totally preclude the possibility of fusion, i.e., cancer, kidney dialysis, or osteopenia are relative contraindications. Other relative contraindications include obesity, certain degenerative diseases, and foreign body sensitivity. Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing. These patients may be at higher risk of implant failure. See also the WARNINGS, PRECAUTIONS AND ADVERSE EFFECTS sections of the product insert.

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

Medos International SARL
Chemin-Blanc 38
2400 Le Locle
Switzerland

DePuy Synthes
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*For recognized legal manufacturer refer to product label

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 095798-180726 DSEM 09/18