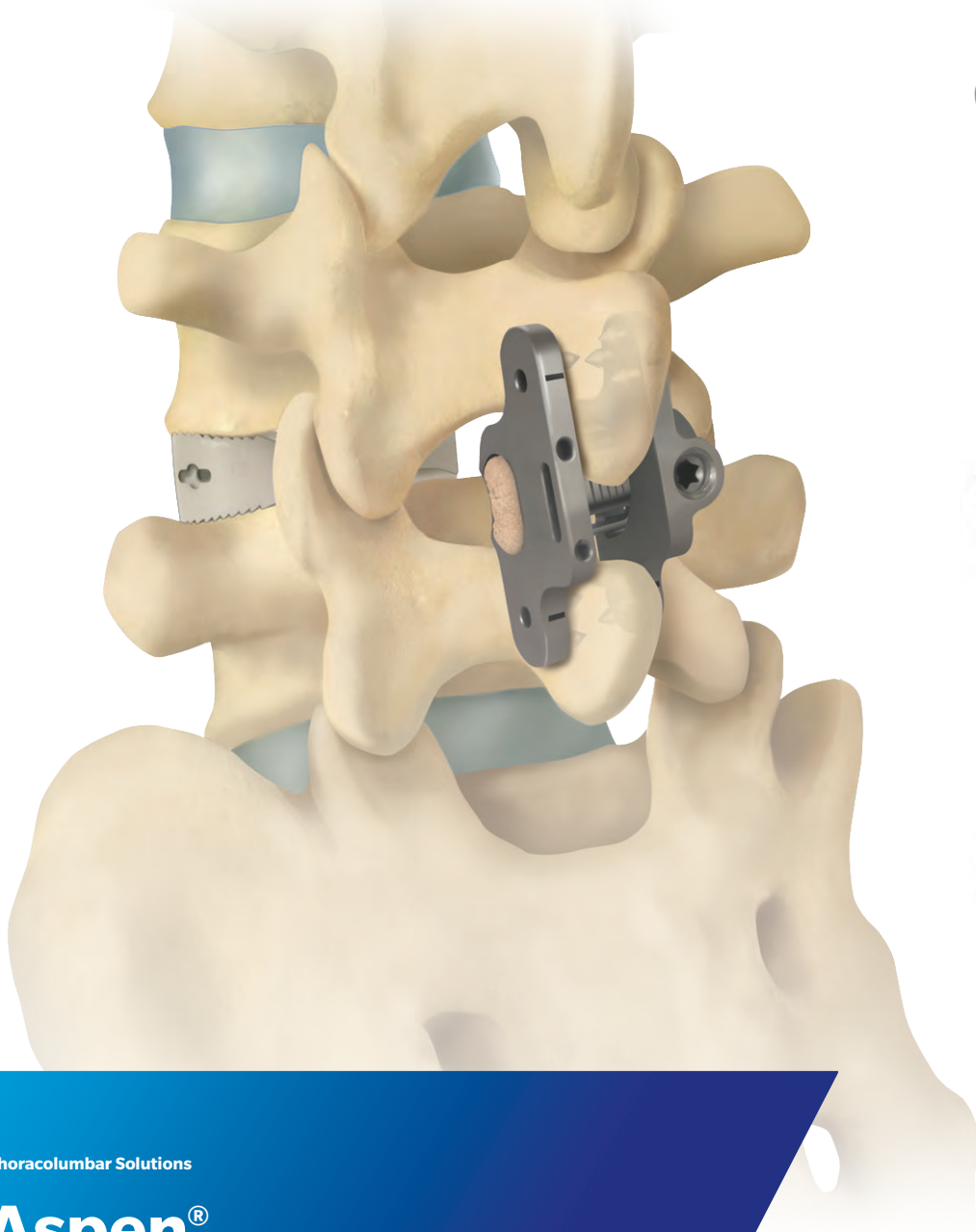




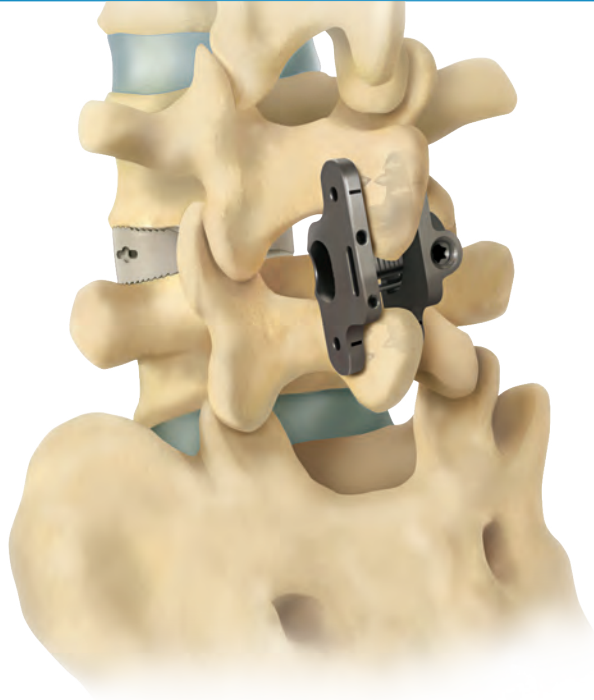
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Thoracolumbar Solutions

Aspen[®] MIS Fusion System

Surgical Technique Guide



*Designed to help optimize
surgical results when implanting
the Aspen MIS Fusion System*

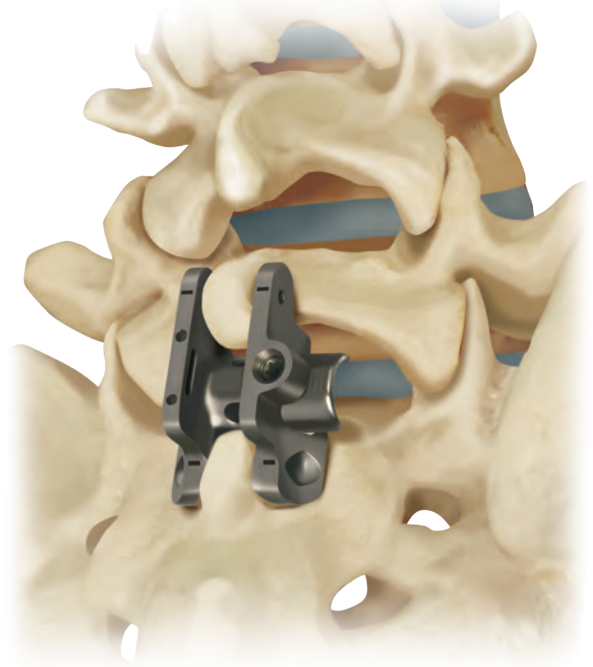


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The following general Surgical Technique Guide is for illustrative purposes only. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as to the best treatment for each patient. Only those individuals with specialized training and experience in spine surgery should attempt to use the Aspen MIS Fusion System. Detailed preoperative clinical and diagnostic evaluation followed by carefully executed surgical technique is essential.

Zimmer Biomet Spine does not practice medicine. Each physician should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training physicians have received.

Refer to the package insert for a complete list of prescribing information, including indications, contraindications, warnings, precautions, potential adverse effects, and patient counseling information. This technique guide was developed in conjunction with health care professionals.

SYSTEM OVERVIEW

The Aspen MIS Fusion System provides robust posterior fixation in the non-cervical spine. It is a less invasive fixation solution to facilitate interbody and posterior fusions.



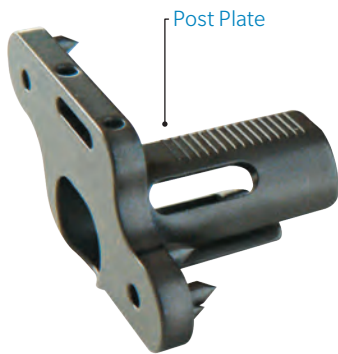
Standard



Medium



Flared 5-1



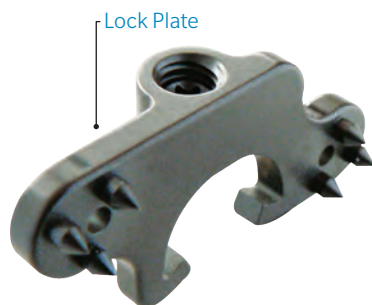
Post Plate



Set Screw



Assembled Plates



Lock Plate

SURGICAL EXPOSURE

Note: Interbody fusion technique is not covered in this technique guide. If performing an interbody fusion, disc preparation and interbody spacer placement are typically performed prior to placement of the Aspen device.

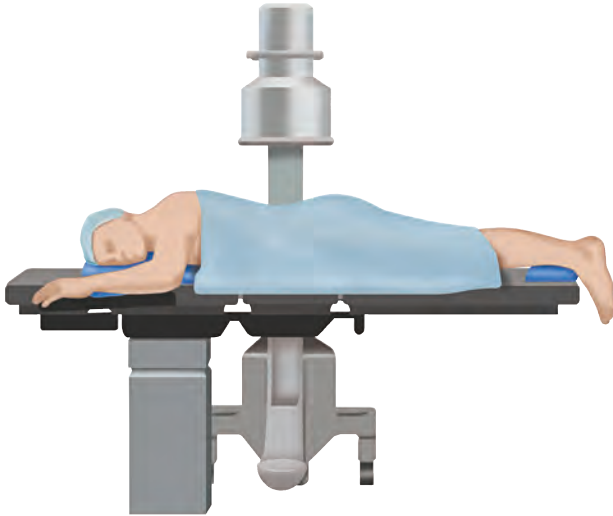


Figure 1

STEP 1

- Position the patient in the prone position on the operating table (**Figure 1**).

Note: The type of frame used depends on the intended procedure, but as a rule of thumb, select the same type of patient positioning that would be chosen if pedicle screws were to be used instead. Avoid hyperlordosing the operative segment.

STEP 2

- Identify the spinous processes at the level to be instrumented using manual palpation and intraoperative imaging.

STEP 3

- Make a midline incision about 3cm–5cm in length to expose the spinous processes at the operative level.

STEP 4

- Elevate the paraspinal musculature and other soft tissue to expose the spinous processes and lamina to the medial border of the facet joints.

SITE PREPARATION

STEP 5

- Clear the fusion site of connective and soft tissues, lightly decorticating the bone surfaces.
- A burr, rongeur or rasp may be used to remove the interspinous ligament.
- The interspinous ligament and supraspinous ligament may optionally be incised or dilated without complete removal. Depending on the surgeon's preferred technique, the supraspinous ligament (SSL) may be left intact, reflected or removed entirely.
- Possible reasons for leaving the SSL intact include:
 - a. Using the intact SSL as a natural inhibitor to prevent over-distraction and guide proper implant sizing.
 - b. Desire to preserve as much of the natural anatomy as possible.
- Possible reasons for removing the SSL include:
 - a. Increased visualization to facilitate a decompression.
 - b. Simplified device implantation.
 - c. Ability to pack bone graft material posterior to the device for a supplemental fusion mass.

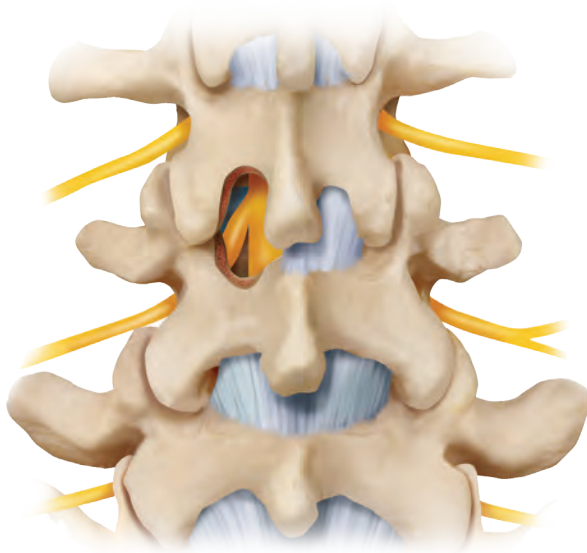


Figure 2

STEP 6

- If a direct decompression is desired, perform a conservative laminotomy, partial facetectomy, foraminotomy or other decompression procedure as needed (**Figure 2**).

Caution: Do not remove excessive amounts of bone, particularly from the base of the spinous processes and midline lamina. Weakening the posterior arch by aggressive bone removal may increase the risk of intraoperative or postoperative fracture of the adjoining spinous processes or posterior arch.

- Decorticate the desired bone surfaces, preparing the fusion sites for bone graft.

STEP 7

- If the facets are hypertrophied and do not allow for proper anterior placement of the implant, the facets may be trimmed. Choosing the Aspen Medium implant, which features a 3mm shorter barrel than the standard Aspen implant, may help avoid the facets.

Caution: Do not perform a complete facetectomy. Preserving a sufficient portion of the facets is required to provide biomechanical stability for axial rotation and transverse shear loads.

SITE PREPARATION (continued)

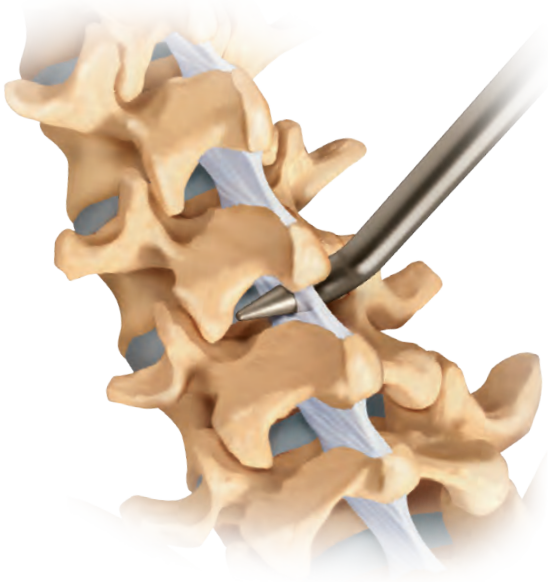


Figure 3

STEP 8

- If the interspinous ligament has been left intact, insert the initial dilator (attaches to the quick connect handle [gray]) and puncture the interspinous ligament, placing it as far anterior as possible (**Figure 3**).

Note: Anterior placement reduces stress on the spinous processes and allows fixation to the thicker, stronger bone at the spinous process/lamina junction. Posterior placement may increase the risk of spinous process fracture.

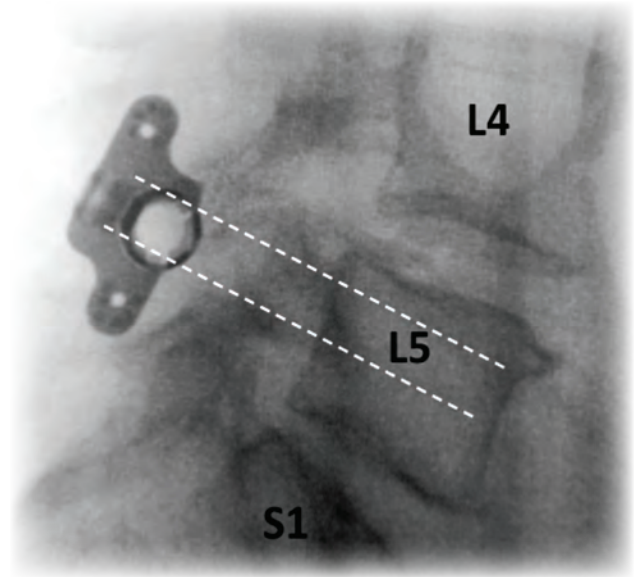


Figure 4

STEP 9

- With the initial dilator in place, confirm that the operative level is correct and placement is appropriate (e.g., anterior placement).

Note: In the lumbar spine, the barrel of the Aspen device should be roughly in line with the pedicle of the inferior level. For example, for an L4–L5 fusion, the barrel of the Aspen device should be roughly in line with the pedicle of L5 (**Figure 4**).

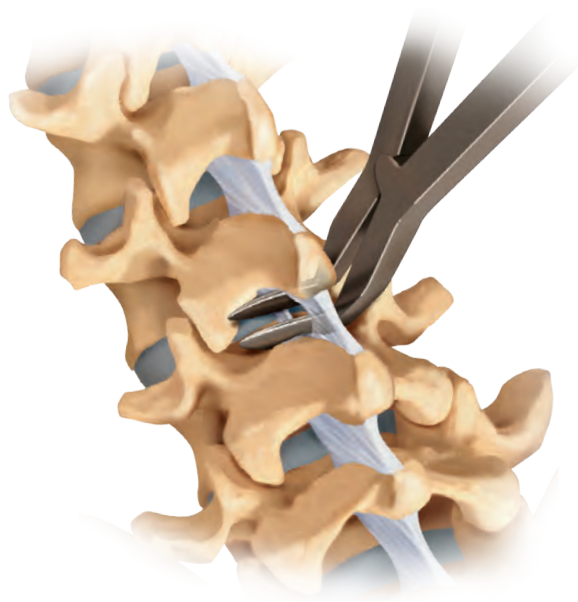


Figure 5



Figure 6a



Figure 6b

STEP 10

- Using the spreader, measure the interspinous separation distance. This measurement will be used to select the appropriate rasp and implant size (**Figure 5**).

Caution: Do not over-dilate the implant space. Excessive force may fracture the spinous processes.

- To ensure optimal tactile feedback during distraction, keep the spreader's ratchet up (disengaged) while dilating the space (**Figure 6a**).
- Once the desired tension is achieved, drop the ratchet down to determine the corresponding rasp and implant size (**Figure 6b**).

SITE PREPARATION *(continued)*

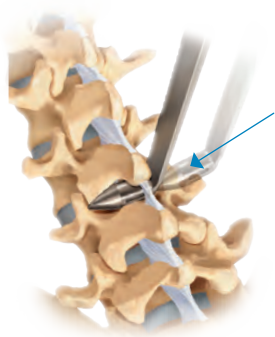


Figure 7

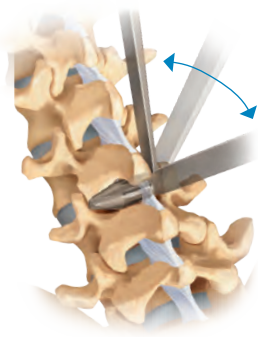


Figure 8



Figure 9

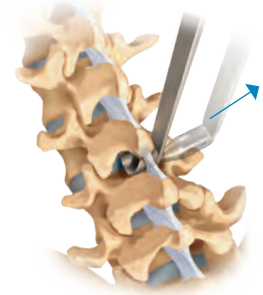


Figure 10

STEP 11

If using the rasps and insertion guide sleeves to facilitate post plate insertion (e.g., if the SSL is left intact):

- Attach the gray handle to the desired rasp size. For initial rasping, it is recommended to use a rasp one size smaller than measured with the spreader.
- After inserting the rasp into the interspinous space, rotate the instrument cephalad and caudad to decorticate the spinous processes and prepare the fusion site (**Figure 7**).
- If necessary, repeat the decortication process with a larger size rasp.
- Remove the rasp from the interspinous space and slide the corresponding sleeve over the rasp (**Figure 8**).
- Insert the rasp/sleeve assembly into the interspinous space (**Figure 9**).

Note: Use caution when inserting both the rasp and sleeve at this stage to ensure that lateral forces being applied to the spinous processes do not cause a fracture.

- Keeping the sleeve in the interspinous space, remove the rasp to create a cannula for the post plate side of the implant (**Figure 10**).

INSERTING THE ASPEN IMPLANT

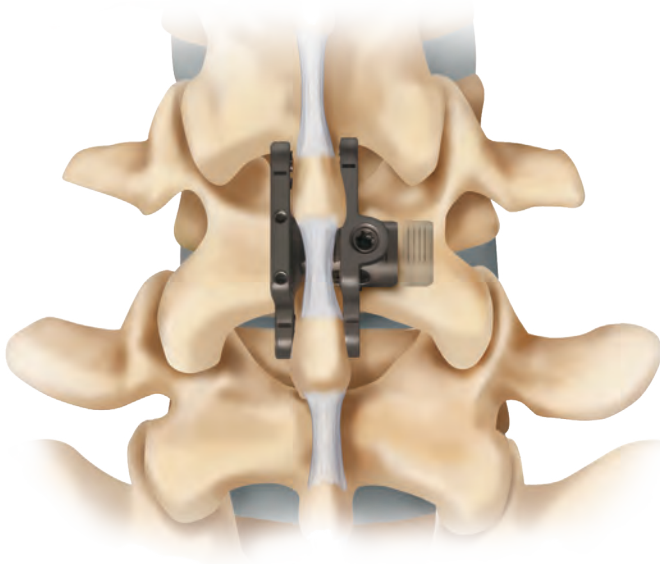


Figure 11



Figure 12

STEP 12

Choose the appropriate size and shape of Aspen implant to best fit the anatomy.

- Barrel diameter: The appropriate barrel diameter should be based on the fit of the previously used rasps and/or spreader.

Note: *Over-sizing the barrel may cause excessive stress on the spinous processes.*

- Barrel length: A standard Aspen barrel (21 mm long) or Aspen Medium* barrel (18mm long) may be chosen. Anatomical factors such as spinous process width and size/location of the facet may influence selection. For example, a standard Aspen barrel may be best suited for a thick spinous process while an Aspen Medium may be preferred for a hypertrophic facet (**Figure 11**).

- Plate flare: The Aspen Flared 5-1* implants feature a 45° flare on one end of the implant assembly. This flare may provide an enhanced fit at L5–S1 (where the S1 spinous process is often smaller and more angled than others) or for any level where a more anterior placement is desired (e.g., at the base of the spinous processes, closer to the lamina junction) (**Figure 12**).

* Special Order

INSERTING THE ASPEN IMPLANT (*continued*)

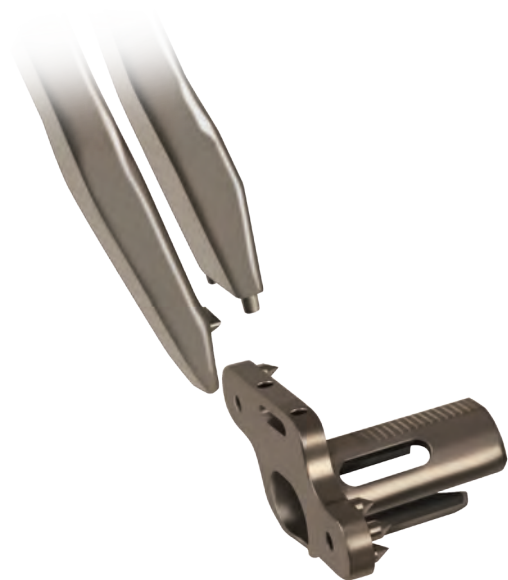


Figure 13

STEP 13

- Attach the post plate implant to the post plate inserter. The small pins on the inserter tip engage the holes in the top aspect of the post plate (**Figure 13**).
- Once the tips are positioned, the adjuster knob must be fully tightened to secure the implant to the inserter. When the adjuster knob is fully tightened, no threads should be visible between the handles (**Figure 14**).

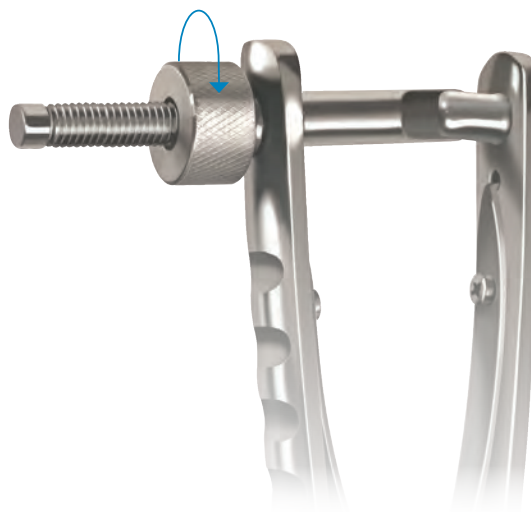


Figure 14

STEP 14

- If desired, pack bone graft material inside the barrel prior to or after post plate implantation.

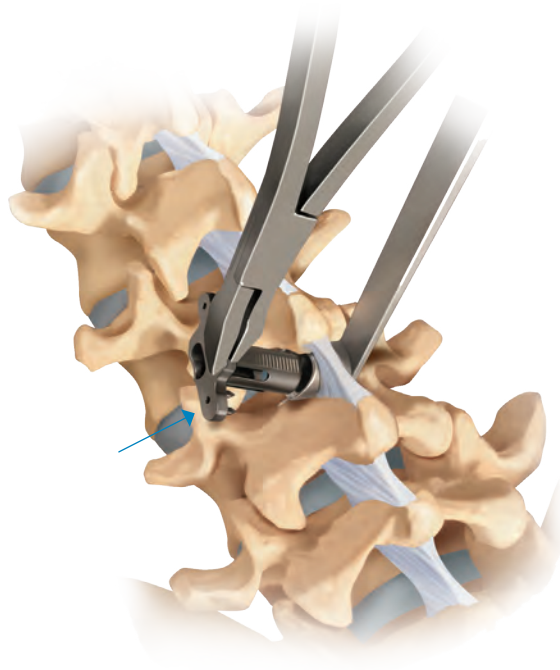


Figure 15

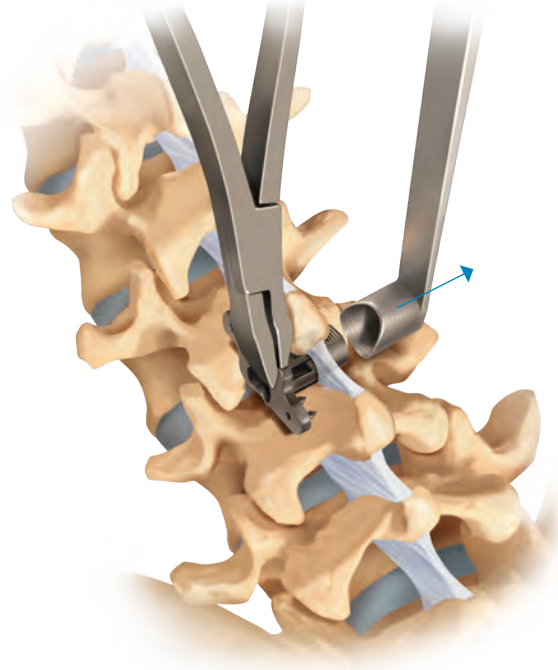


Figure 16

STEP 15

Three techniques are available for placement of the barrel of the post plate into the interspinous space.

Preferred Technique 1

- From the opposite side of the sleeve's handle, introduce the implant barrel into the sleeve's cannula (**Figure 15**).
- Rotate the implant into its final position while simultaneously removing the sleeve from the interspinous space (**Figure 16**).

Optional Technique 2

- If the sleeve is not being used, begin inserting the post plate of the implant rotated approximately 45° to 90° in the sagittal plane.
- In this orientation, the open edge of the barrel can be guided into the space. Rotate the implant back into final position while simultaneously pushing the barrel into the interspinous space.

Optional Technique 3

- If the supraspinous ligament has been reflected or removed and the interspinous ligament excised, the implant may be inserted from the direct-midline approach, rather than from a paramedian approach.

Note: The more dorsally positioned end of the plate may be oriented either cephalad or caudad (corresponding to the post plate situated on the patient's left or right, respectively). Cephalad orientation often allows the Z-shape of the plates to better contour to the slant of the laminae.

INSERTING THE ASPEN IMPLANT (continued)



Figure 17

STEP 16

- Choose the lock plate that corresponds to the post plate size. Prior to attaching the inserter, ensure that the set screw has been backed up, flush with the top of the lock plate, to allow the plate to slide unobstructed onto the barrel.

Note: To expedite the surgery, back up the set screw in each of the set's lock plates at the start of the procedure.

- Attach the lock plate to the lock plate inserter.
- The peg side of the inserter fits inside the set screw while the curved portion surrounds the set screw housing (**Figure 17**).

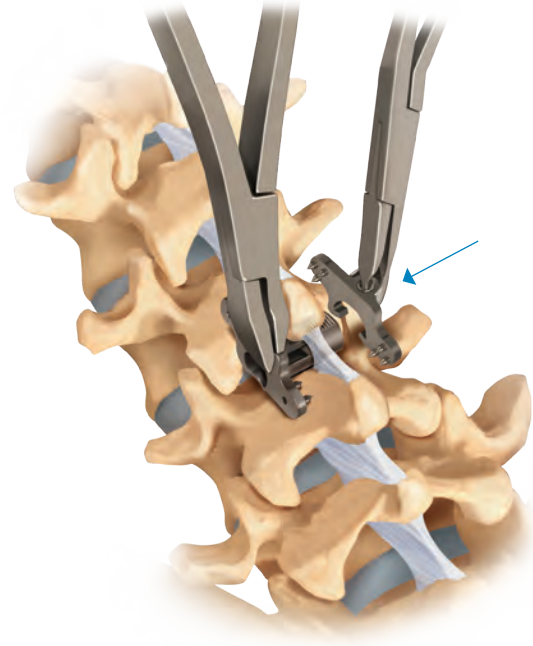


Figure 18

STEP 17

- Slide the lock plate over the barrel until it comes in contact with the spinous processes (**Figure 18**).

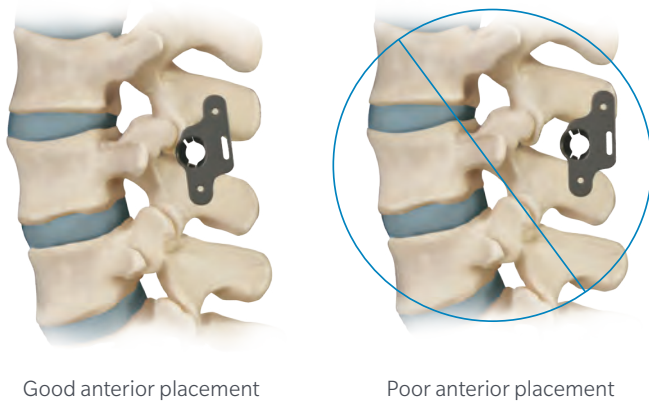


Figure 19

STEP 18

- Before compressing the plates and tightening the set screw, ensure that the device is placed as far anteriorly as possible, and that the plate does not protrude above the lumbodorsal fascia.
- Confirm correct placement with radiograph (**Figure 19**).

Note: Avoid implant placement too far posterior, as this may increase the risk of spinous process fracture.

- The lock plate will angulate up to $\pm 10^\circ$ in the coronal plane to accommodate different spinous process widths (**Figure 20**).



Figure 20

STEP 19

- Using the laser-marked lines just above the implant's divots for reference, insert the conical tips of the compressors into the lateral divots in each plate. Once the compressors are engaged with the plates, the lock plate inserter and post plate inserter may be removed.

INSERTING THE ASPEN IMPLANT (continued)

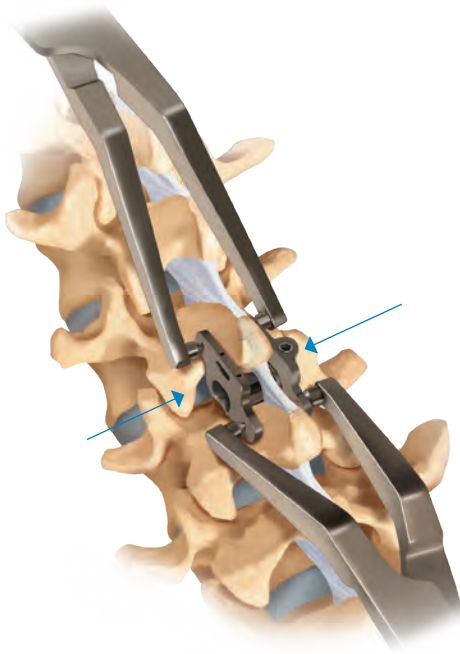


Figure 21

STEP 20

- Using the compressors, clamp the plates against the spinous processes, driving the spikes into the bone (**Figure 21**).
- Squeeze both compressors simultaneously or alternate back and forth.
- Compress until the spikes are fully seated into the bone.

Note: Take care not to over-compress and risk crushing or weakening the cortex, thereby increasing the risk of spinous process fracture (i.e., maximum compression force does not necessarily equate to better fixation).

- Visually confirm that the spikes are fully seated into the bone, with good apposition of the plates against the sides of the spinous processes.

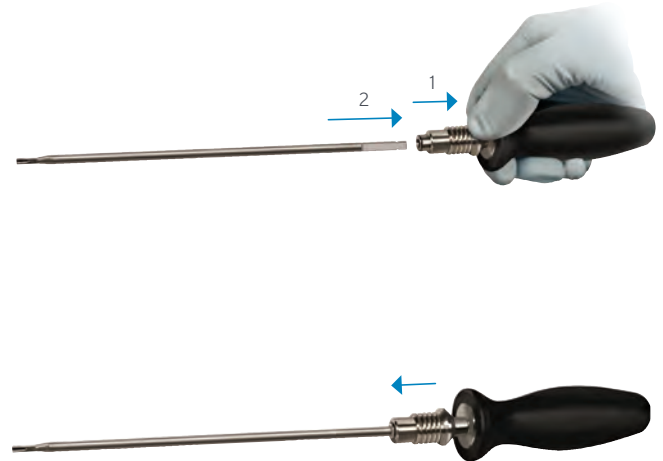


Figure 22

STEP 21

- Attach the set screw driver shaft to the 30in-lb (3.4Nm) torque limiting handle (black) (**Figure 22**).
- Place the set screw driver into the set screw. Ensure that the driver tip is fully seated into the set screw to prevent rounding of the set screw's hexalobe drive features.
- While keeping the compressors engaged with the plates to serve as a counter-torque, tighten the set screw until the torque handle clicks twice (**Figure 23**).

Note: To ensure that the set screw fully engages the post plate, visually confirm that the barrel protrudes beyond the lateral edge of the lock plate's set screw housing.

BONE GRAFTING AND CLOSURE

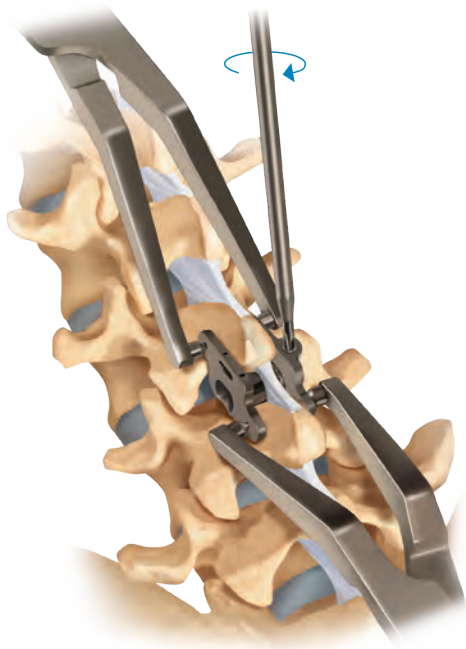


Figure 23

STEP 22

- Remove the compressors.
- Manually and visually inspect the implant assembly to confirm secure fixation.
- Confirm proper placement of the implant using fluoroscopy.

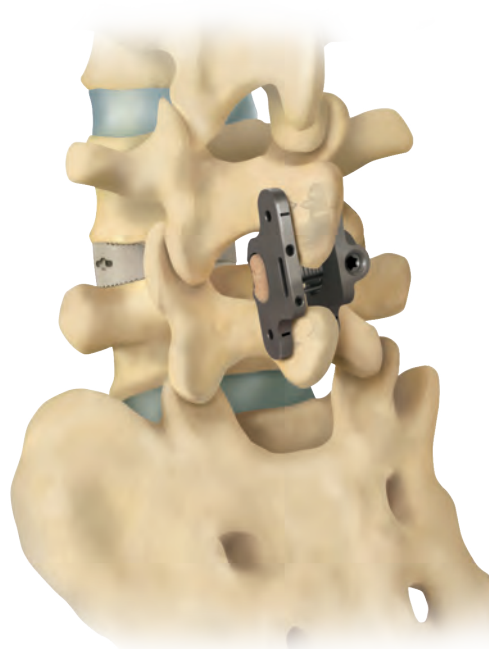


Figure 24

STEP 23

- If fusing through the facets, decorticate articular surfaces and place bone graft in the usual manner. If desired, additional posterior bone grafting material may be placed across the lamina, around the implant and/or in the posterolateral gutter.
- If not already done, bone graft material may be packed inside the barrel prior to placement of the implant (**Figure 24**).
- If the supraspinous ligament was resected, bone graft material may be packed posterior to the device between the tips of the spinous processes.
- If the supraspinous ligament was reflected, it may be sutured back to the tips of the spinous process. The fascia may be closed back to the supraspinous ligament.
- After the construct is implanted and bone graft completed, close the surgical site using standard techniques.

REMOVING THE ASPEN IMPLANT

-
1. If a nonunion develops, or if the components loosen or break, the device should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed nonunion of bone will result in excessive and repeated stresses on the implant and anatomy. By the mechanism of fatigue, these stresses can cause eventual loosening or breakage of the device or fracture of the underlying bone.
 2. Use the set screw driver (provided in the standard Aspen surgical instrument set) to loosen the locking set screw. Although the Aspen-specific set screw driver is recommended, a T10 Torx driver may be used as a substitute.
 3. The plates can then be separated with a Cobb elevator or similar instrument and removed from the spinous processes. Explanted surgical implants must never be reused.

INSTRUMENTS



Quick Connect Handle, Gray (2) PART NUMBER
6200-1108



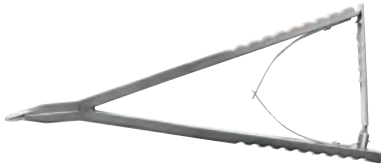
Post Plate Inserter PART NUMBER
6200-2005



Initial Dilator PART NUMBER
6200-1400



Lock Plate Inserter PART NUMBER
6200-2006



Spreader PART NUMBER
6200-3001



Compressor (2) PART NUMBER
6200-1115



Rasp

SIZE	PART NUMBER	SIZE	PART NUMBER
8 mm	6200-1608	14 mm	6200-1614
10 mm	6200-1610	16 mm	6200-1616
12 mm	6200-1612	18 mm	6200-1618



Set Screw Driver Shaft (2) PART NUMBER
6200-1104



Insertion Guide Sleeve

SIZE	PART NUMBER	SIZE	PART NUMBER
8 mm	6200-1508	14 mm	6200-1514
10 mm	6200-1510	16 mm	6200-1516
12 mm	6200-1512	18 mm	6200-1518



Torque Limiting Handle 30in-lb, 3.4Nm, Black (2) PART NUMBER
6200-1400

IMPLANTS

Aspen Standard

SIZE	LOCK PLATE	POST PLATE	SET SCREW
8 mm	6201-0008-001	6211-0008-003	6201-0001-002
10 mm	6201-0010-001	6211-0010-003	
12 mm	6201-0012-001	6211-0012-003	
14 mm	6201-0014-001	6211-0014-003	
16 mm	6201-0016-001	6211-0016-003	
18 mm	6201-0018-001	6211-0018-003	



Aspen Medium

SIZE	LOCK PLATE	POST PLATE	SET SCREW
6 mm	6201-0006-001	6212-0006-003	6201-0001-002
8 mm	6201-0008-001	6212-0008-003	
10 mm	6201-0010-001	6212-0010-003	
12 mm	6201-0012-001	6212-0012-003	
14 mm	6201-0014-001	6212-0014-003	



Aspen Flared 5-1

SIZE	LOCK PLATE	POST PLATE	SET SCREW
8 mm	6251-0008-001	6251-0008-003	6201-0001-002
10 mm	6251-0010-001	6251-0010-003	
12 mm	6251-0012-001	6251-0012-003	
14 mm	6251-0014-001	6251-0014-003	
16 mm	6251-0016-001	6251-0016-003	
18 mm	6251-0018-001	6251-0018-003	



IMPORTANT INFORMATION ON THE ASPEN MIS FUSION SYSTEM

Device Description

The Aspen MIS Fusion System is a posterior attachment spinal fixation system composed of spinous process plates, dedicated surgical instruments and sterilization cases. The components are used to build a construct to provide stabilization of spinal segments in the thoracic, lumbar and sacral spine to support fusion. The Aspen device is part of the Zimmer Biomet Spinal Fixation System, which offers the surgeon a variety of implant components from which to assemble a suitable construct according to each individual patient's needs and requirements. It is essential to use Zimmer Biomet implants with their specifically designed instruments. After a solid fusion occurs, the system serves no functional purpose and should be removed. Removal is indicated because the implants are not intended to transfer or support forces developed during normal activities. However, any decision to remove the device must be made by the physician and the patient, taking into consideration the patient's general medical condition and the potential risk to the patient of a second surgical procedure.

Indications for Use

The Aspen MIS Fusion System is intended to be used to help provide immobilization and stabilization of spinal segments as an adjunct to fusion of the thoracic, lumbar and/or sacral spine. The system is intended for use with autograft or allograft.

The Zimmer Biomet Spinal Fixation System is intended for posterior, non-cervical (T1–S2/ilium) pedicle and non-pedicle spinal fixation, to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following instabilities or deformities: 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); spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis and/or lordosis), tumor, pseudarthrosis and failed previous fusion.

The Aspen device is a posterior, non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1–S1). It is intended for plate fixation/attachment to spinous processes for the purpose of achieving supplemental fusion in the following conditions: DDD, spondylolisthesis, trauma (i.e., fracture or dislocation) and/or tumor. The Aspen device is intended for use with bone graft material and not intended for stand-alone use.

Contraindications

Contraindications may be relative or absolute. The choice of a particular device must be carefully weighed against the patient's overall evaluation. Circumstances listed below may reduce the chance of a successful outcome. Contraindications include, but are not limited to:

- An allergy to titanium or cobalt chrome alloys, or foreign body sensitivity. Where material sensitivity is suspected, appropriate tests must be performed prior to implantation.
- Known or suspected infection/immune system incompetence, including acute or chronic infectious diseases of any etiology or localization.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to, severe osteoporosis involving the spine, bone absorption, osteopenia, active infection at the site or certain metabolic disorders affecting osteogenesis.
- Morbid obesity. An overweight or obese patient can produce loads on the spinal system, capable of leading to failure of the fixation of the device or failure of the device itself.
- Any neuromuscular deficit which places an unusually heavy load on the device during the healing period.
- Open wounds.
- Pregnancy.
- Any other medical or surgical condition which would preclude the potential benefit of spinal surgery, such as the presence of congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood cell (WBC) count or a marked left shift in the WBC differential count.
- Any case requiring the mixing of components from other manufacturers' systems.
- Any case requiring the mixture of stainless steel with titanium, or stainless steel with cobalt chrome implant components.
- Fever or leukocytosis.
- Signs of local infection or inflammation.
- Previous history of infection.
- Alcoholism or heavy smoking.
- Senility, mental illness or substance abuse, of a severity that the patient may ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.

IMPORTANT INFORMATION ON THE ASPEN MIS FUSION SYSTEM (*continued*)

- Any patient unwilling to follow postoperative instructions.
- Inadequate tissue coverage over the operative site.
- The Aspen device is also contraindicated for incompetent or missing posterior arch (e.g., laminectomy, pars defect, severe osteoporosis).

Warnings

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5–S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

A successful result is not always achieved in every surgical case. This fact is especially true in spinal surgery, where many extenuating circumstances may compromise the results.

Precautions

- The Aspen implants are for single use only. Never reuse any implant, even if it appears unmarked or undamaged. Reuse of the implant components may result in reduced mechanical performance, malfunction or failure of the device. Any implant implanted and then removed must be discarded.
- Use only new implants for each case.
- The implantation of spinal fixation systems must only be performed by experienced spinal surgeons with specific training in the use of this system due to the technically demanding procedure presenting a risk of serious injury to the patient.
- Based on the fatigue testing results, the physician/surgeon must consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system.
- Preoperatively: The surgeon must be fully conversant with all aspects of the surgical technique and know the indications and contraindications of this type of implant. The surgeon must have acquainted himself before the operation with the specific technique for insertion of the product, which is available from the manufacturer. As part of the preoperative examination, the surgeon must check that no biological, biomechanical or other factors will affect the correct conduct of the operation and the postoperative period. An appropriate range of implant sizes must be available at the time of the operation.
- Intraoperatively: The correct selection of the type and size of implant appropriate to the patient and the positioning of the implant are extremely important.
- Postoperatively: Patients must be informed of the precautions to be taken in their everyday life to guarantee a maximum implant service life. It is recommended that regular postoperative follow-up is undertaken to detect early signs of failure of the implants and to consider the action to be taken.
- Deterioration of the device after bone consolidation cannot be considered to constitute a dysfunction or deterioration in the characteristics of the implants. The implant can be removed after bony healing.
- The Aspen device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. The Aspen device has not been tested for heating or migration in the MR environment.

Disclaimer: This document is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. Please refer to the package inserts for important product information, including, but not limited to, indications, contraindications, warnings, precautions, adverse effects, and patient counseling information.



Manufactured by:
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