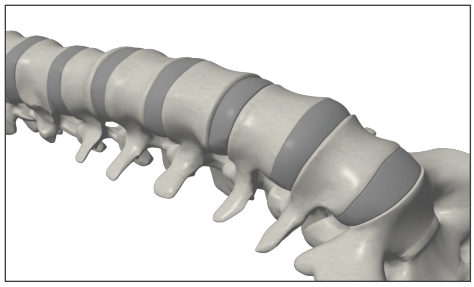
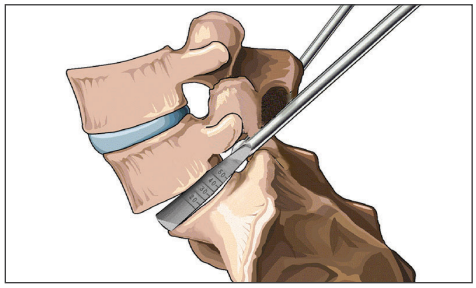
Polymer Lumbar Disc Spacer

SURGICAL TECHNIQUE GUIDE

A-SPINE

Contents





Introduction

The posterior / anterior spinal fusion surgical technique has been well established for many years and in this time a wide range of instruments and implants have been utilised. In recent years posterior lumbar interbody fusion (PLIF) cages have been used in order to restore the patient's original disc height, aid with stabilisation of the affected segment/s and provide an environment that will permit solid, bony fusion.
Use of pedicle screw fixation is strongly recommended in order to provide additional stability and improve the success rate of bone healing and fusion.

Design Rationale

1. The implant has been designed to be rotated 90° after insertion to avoid over-stretching the Posterior Longitudinal Ligament (PLL).
2. Window for placement of bone graft material to facilitate fusion through the cage.
3. Simple yet comprehensive instrumentation to prepare the disc space and insert the prostheses.
4. Serrated surfaces to maximise endplate contact and minimise the risk of implant migration.

PEEK Advantages

1. Bio-compatible
2. High performance composite material which is lighter than Ti alloy.
3. Avoids potential patient sensitivity to metallic implant materials.
4. Radiolucency under X-ray, CT or MRI examination for better visualization of bone tissue integration around the fusion site.

Indications

The diseases use with autogenous bone graft for spinal interbody fusion operation, including:

1. Use for Degenerative Disc Disease (DDD) and Degenerative Lumbar Scoliosis at 1 or 2 levels from L1 to S1, e.g. primary laminectomy for decompression
2. Grade 1 spondylolisthesis or retrolisthesis at the involved level(s)
3. Revision surgery for failed column operation or post-operation instability
4. Stenosis
5. Pseudarthrodesis at the lumbar
6. Posterior or anterior approach for lumbar

Contraindications

- Patients with fever or leukocytosis
- Patients with infections associated with the spine (e.g. spondylodiscitis)
- Patients with a history of material allergy or who tend to react to foreign bodies
- Patients whose general medical or psychological condition is unfavorable for- or could be worsened by the procedure; careful consideration is required on the part of the treating physician/surgeon for these patients
- Patients with inadequate bone quality or quantity (e.g. severe osteoporosis, osteopenia, osteomyelitis)
- Pregnancy

Sterilization

The cage had been sterilized by gamma radiation at least 25 kGy dose. It should avoid contaminating while operation process. It is necessary to exchange if the packaging has been broken without reason. The instruments are provided Non-Sterile to hospital. A-SPINE suggests the device should be sterilized via steam sterilization (under 121 ℃/ 250 ℉, 20 PSIG for 30 mins) to assure SAL (10^{-6}).

Components

The implant is made of Polyetheretherketone (PEEK) in compliance with ASTM F2026 and the maker is made of Tantalum in compliance with ASTM F560.

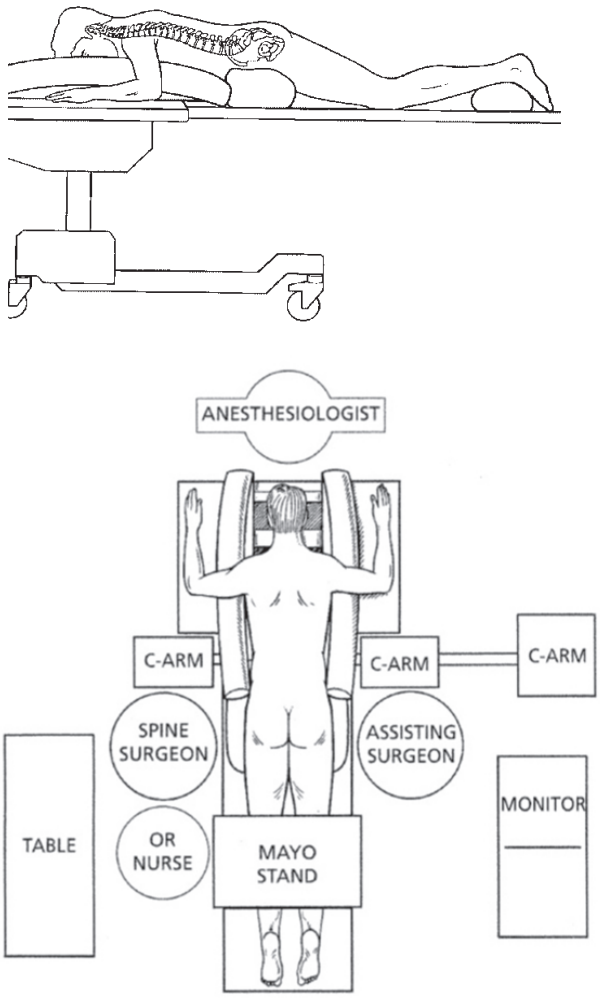
Surgical Technique

Preoperative preparation

Preoperative CT/MRI images are used to confirm lesion location, vertebrae dimensions, as well as the appropriate size of the Vigor PEEK Lumbar Disc Spacer for preoperative reference. However, the size of the actual implant used is subject to evaluation by the surgeon intraoperatively.

Patient Position

The patient is positioned in prone position with the abdomen free from pressure. This position aids in the maintenance of normal lumbar lordosis and the reduction of abdominal compression, minimizing epidural venous bleeding (Figure 1).
C-arm Fluoroscopic image intensifier should be used throughout the surgery.



Patient position of the posterior lumbar operation

Figure 1

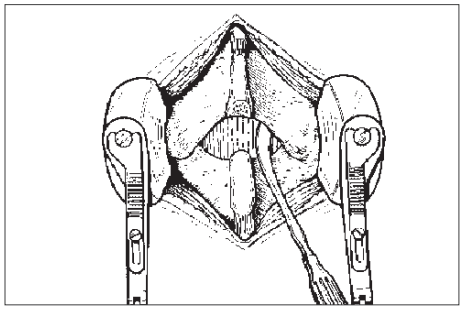


Figure 2

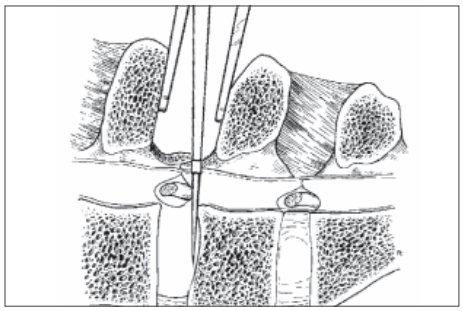


Figure 3

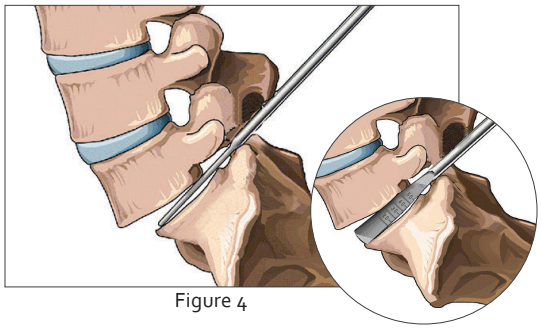


Figure 4

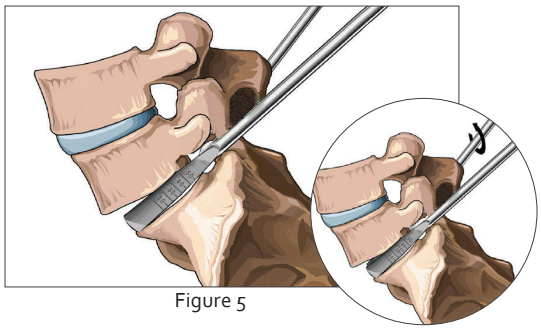


Figure 5

01 Disectomy

Laminectomy or bilateral laminectomy was performed using the ***Nerve Retractor (421-3501~421-3504)*** to protect the dura mater.
The affected intervertebral disc was removed(Figures 2 and 3).

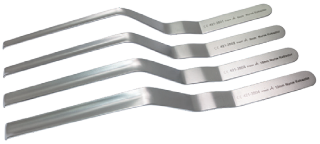
Use a ***T-handle (406-0101***) to connect the ***Distractor with Shaver (421-1607~421-1616)*** for operation.

The appropriate Distractor with Shaver was inserted parallel into the disc space and rotated 90° to the right or left to initially disperse the vertebral body (Figure 4).

At first, insert the smallest size to disperse the vertebral body, then insert a larger size and repeat the above actions until the disc space is restored (Figure 5).

NOTE:

Retractors using razors can promote the removal of the surface layers of the nucleus pulposus and cartilage endplates, but excessive cleaning can weaken the endplates and cause sinking and lead to loss of segmental stability.



421-3501~421-3504

Nerve Retractor
6,8,10,12mm

406-0101

T-Handle

421-1607~421-1616

Distractor Shaver

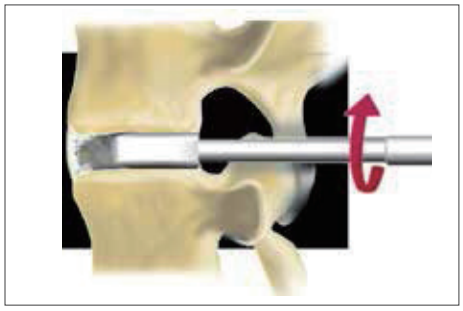


Figure 6

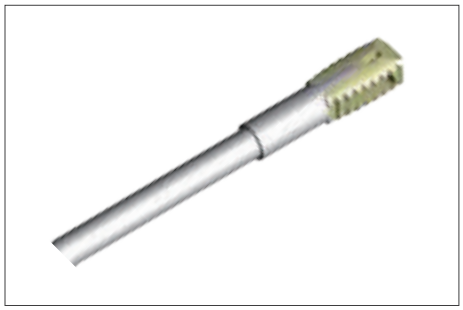


Figure 7

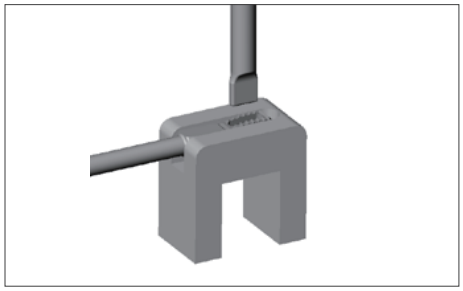


Figure 8

02 Trial

Assemble T-handle (406-0101) and Trials (422-0640~422-0649), insert it into disc with the narrow height of the trial facing the vertebral endplate.
When the Trial reaches the appropriate depth, rotate 90°to distract and assess height, and the handle can be rotated 90° counterclockwise to release for Trial removal.
Use the larger size Trial to repeat previous steps until adequate anterior height is obtained (Figure 6).

Implanting the Polymer Lumbar Disc Spacer

The proper size of Polymer Lumbar Disc Spacer connects to the top of the Lumbar PEEK Insertor (422-1712, 422-1713) and secured by ***Lumbar PEEK Screw Driver (422-1710)*** (Figure 7).

Cat.No.	422-1712 422-1713	
Description	4mm Lumbar PEEK Insertor 6mm Lumbar PEEK Insertor	
Cage Height	7-11 12-16	

When the spinal fusion need using bone graft, it should be put into the open cavities of the Polymer Lumbar Disc Spacer.
The general procedure is putting the Polymer Lumbar Disc Spacer into the ***Bone Graft Template (422-3202)*** and then fills with the bone graft by ***Bone Graft Impactor (422-3003)*** (Figure 8).

422-0640~422-0649

Trial

422-1710

Lumbar PEEK Screw Driver

422-3202

Bone Graft Template

422-3003

Bone Graft Impactor

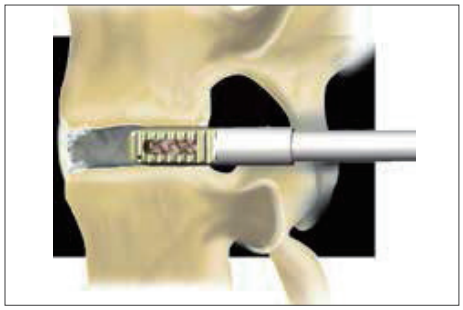


Figure 9

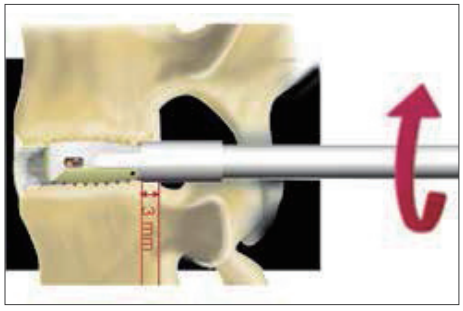


Figure 10

Insert the implant into the disc space within a horizontal direction. ***Slide Hammer (428-4001)*** can be used for auxiliary insertion (Figure 9).
Once the desired depth is achieved, the implant is rotated 90° in order to restore the desired intervertebral height (Figure 10).

Rotate the Lumbar PEEK Screw Driver counterclockwise to release implant.

Use the radiographic AP and Lateral view to confirm the correct position.
If the cage needs to be adjusted position, use the Final ***Impactor (405-3001)*** to tap gently.

CAUTION:
The surgeon should ensure that the final position of the implant is no closer than 3mm to the posterior edge of the vertebrae.

Once cages have been inserted bilaterally additional bone graft material can be packed around the cage it is strongly suggested that pedicle screw fixation is used to augment fixation of the Vigor Peek Lumbar Disc spacer. Compression should be applied to the pedicle screw fixation system prior to final tightening to promote bony integration.

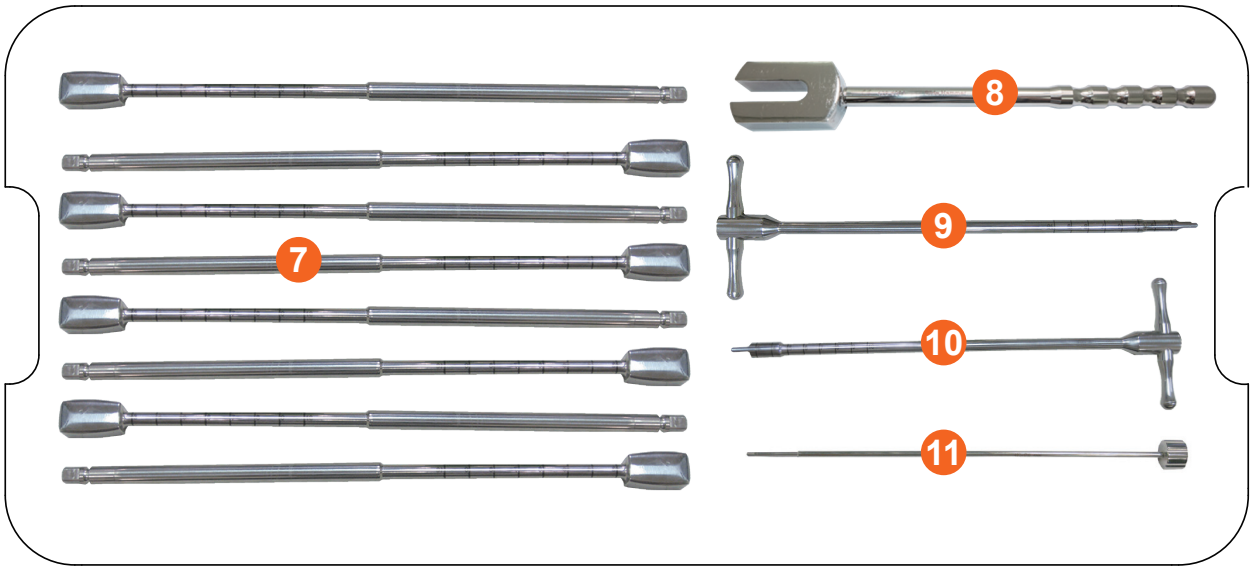
428-4001
Slide Hammer

405-3001
Final Impactor

Instrument Set

Instrument Tray 1

Cat.No.	Description		Q'nty
1 421-1607	7mm		1
421-1608	8mm		1
421-1609	9mm		1
421-1610	10mm		1
421-1611	11mm		1
421-1612	12mm	Distractor with Shaver	1
421-1613	13mm		1
421-1614	14mm		1
421-1615	15mm		1
421-1616	16mm		1
2 422-3003	Bone Graft Impactor		1
3 405-3001	Impactor		1
4 406-0101	T-Handle		1
5 422-3202	Bone Graft Template		1
421-3501	6mm		1
421-3502	8mm		1
6 421-3503	10mm	Nerve Retractor	1
421-3504	12mm		1

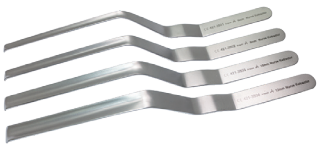


Instrument Tray 2

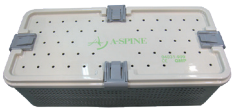
Cat.No.	Description		Q'nty
7 422-0640	7mm		*
422-0641	8mm		*
422-0642	9mm		1
422-0643	10mm		1
422-0644	11mm		1
422-0645	12mm	Turnable Trial	1
422-0647	14mm		1
422-0649	16mm		1
8 428-4001	Slap Hammer		1
9 422-1712	4mm Lumbar PEEK Insertor		1
10 422-1713	6mm Lumbar PEEK Insertor		1
11 422-1710	Lumbar PEEK Screw Driver		3

*Option

Instruments

Cat.No.	Description		
405-3001	Impactor		
406-0101	T-Handle		
421-1607 421-1608 421-1609 421-1610 421-1611 421-1612 421-1613 421-1614 421-1615 421-1616	7mm 8mm 9mm 10mm 11mm 12mm 13mm 14mm 15mm 16mm	Distractor with Shaver	
422-0640 422-0641 422-0642 422-0643 422-0644 422-0645 422-0647 422-0649	7mm * 8mm * 9mm * 10mm 11mm 12mm 14mm 16mm	Turnable Trial	
421-3501 421-3502 421-3503 421-3504	Nerve Retractor	6mm 8mm 10mm 12mm	
422-1710	Lumbar PEEK Screw Driver		
422-3003	Bone Graft Impactor		

*Option

Cat.No.	Description	
422-1712	4mm Lumbar PEEK Insertor	
422-1713	6mm Lumbar PEEK Insertor	
422-3202	Bone Graft Template	
428-4001	Slap Hammer	
99900-034	X`Plo Case, Metal Lid	
99902-034	X`Plo Case, Plasty Lid *	

STERILIZATION:

The cage had been sterilized by gamma radiation at least 25 kGy dose. It should avoid contaminating while operation process. It is necessary to exchange if the packaging has been broken without reason.

The instruments are delivered non sterile. Before use needed cleaned and sterilized recommended to be steam sterilized refer to "A-SPINE Reprocessing Manual" following process parameters:

Steam Wrapped Gravity Cycle at 121 °C/250 °F for 30 minutes.

If need more information, the "Intended for Use" and "A-SPINE Reprocessing Manual" can be downloaded from A-SPINE official website: http://www.aspine.com.tw/

Implants

Vigor PEEK Disc Spacer (M)

Cat.No.	Description	
594-07096	Vigor PEEK Disc Spacer (M)	5° / H9 x L 24 x W7 mm
594-08106	Vigor PEEK Disc Spacer (M)	5° / H10 x L 24 x W8 mm
594-09116	Vigor PEEK Disc Spacer (M)	5° / H11 x L 24 x W9 mm
594-10126	Vigor PEEK Disc Spacer (M)	5° / H12 x L 24 x W10 mm
594-11146	Vigor PEEK Disc Spacer (M)	5° / H14 x L 24 x W11 mm
594-12166	Vigor PEEK Disc Spacer (M)	5° / H16 x L 24 x W12 mm

NOTE

NOTE

A-SPINE

A-SPINE Asia Co.,Ltd.
20F., No.80, Section 1, Chenggong Road, Yonghe District,
New Taipei City 234634, Taiwan
Tel:+886-2-2926-7088 Fax:+886-2-2926-7396
E-mail:service@aspine.com.tw www.aspine.com.tw

T-PDS-009-CE/2022-04-19