# Polymer Lumbar Disc Spacer

SURGICAL TECHNIQUE GUIDE





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### Introduction

The posterior / anterior spinal fusion surgical techniques have been developed for many years, and numerous types of instruments were made, the clinical treatment is good, but surgical technique is very difficult; the new development of spinal surgery is implanting the disc spacer now. Post-operation can ameliorate the patient' symptom and maintain the bodys'tabilization immediately, improve the success rate of the bone healing and fusion.

### 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

- 1. Patients with fever or leukocytosis
- 2. Patients with infections associated with the spine (e.g. spondylodiscitis)
- 3. Patients with a history of material allergy or who tend to react to foreign bodies
- 4. 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
- 5. Patients with inadequate bone quality or quantity (e.g. severe osteoporosis, osteopenia, osteomyelitis)
- 6. Pregnancy

### Sterilization

- Polymer Lumbar Disc Spacer has been sterilized with gamma radiation (SAL 10<sup>-6</sup>) (dose 25 KGy).
- 2. When the sterile package is damaged, please return this product to us for exchange.

### Surgical Technique

#### O Preoperative preparation

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

#### O Patient Position

Patient is positioned in prone position with abdomen free from pressure. This position aids in the maintenance of normal lumbar lordosis and the redu-ction of abdominal compression, minimizing epidural venous bleeding (Fig. 1). C-arm Fluoroscopic image intensifier is used to supervise throughout the surgery.



patient position of the posterior lumbar operation Figure 1



Figure 2



Figure 3



Figure 4



#### Figure 5

It is recommended that pedicle screws be placed at this time by standard technique.

A laminectomy or bilateral laminectomies is performed according to patient necessity.

### O Discectomy and Endplate Preparation

#### • Step 1

The affected disc is excised in routine manner

Use the *Nerve Retractor* (421-3501 ~ 421-3504) to protect Dura mater.

#### • Step 2

Use a *T-handle (406-0101)* to connect the Distractor Shaver for operation.

Insert the flat side of the **7mm Distractor Shaver(421-1607)** into the affected disc and rotate it 90° to the right or left to restore disc height.



421-3501~421-3504

Nerve Retractor 6,8,10,12mm



Distractor Shaver 7~16mm



406-0101 T-Handle



Figure 6

#### O Trial

The Trial from 7mm to 14mm is equivalent to implant size , check the size from small *Trial 7mm (422-0660)* to step up size (~ *422-0667*).

Measure the disc space for deciding the cage size by the Trial.

#### NOTE:

It may result in lordosis and loss stability when Trial is undersized.

However, using an oversized Trial may be difficult to insert or even destroy the vertebral endplate.



Figure 7

It have two kinds of Slide Hammer. Use the *Strike Cover (428-4003)* to buckle the terminal end of Trial when use the *Slide Hammer (428-4001)* to knock the Trial.

Another *Slide Hammer (428-4002)* just need to buckle the terminal end of Trial, and then move the central hammer part to knock the Trial. The *Strike Cover (428-4003)* 







Slide Hammer



428-4002

Slide Hammer



428-4003

Strike Cover

422-0660~422-0667

7~14mm Trial

### O Implanting the Polymer Lumbar Disc Spacer







#### • Step 1

The proper size of Polymer Lumbar Disc Spacer implant connect to the top of the *Lumbar PEEK Insertor(422-1701)* and tighten the inner shaft (Fig. 8 & 9 & 10).



Figure 11

#### • Step 2

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 *X'Plo Bone Graft Template (422-3203)* and then fills with the bone graft by *Bone Graft Impactor (422-3003)* (Fig. 11).



Figure 12

#### Step 3

Use the *Slide Hammer (428-4001)* to knock the insertor, and insert the cage slowly.

Hold the inserter firmly and allow the Ti spacer teeth face to the endplate (Fig. 12).



422-1701

Lumbar PEEK Insertor



422-3203 X'Plo Bone Graft Template

422-3003 Bone Graft Impactor



Figure 13

#### • Step 4

If the position not ready, we could use the *Impactor* (405-3001) to modify the Polymer Lumbar Disc Spacer position and let cage's teeth surface close to the endplate. (Fig. 13).

#### NOTE:

The PLIF implant approach to the lumbar spine vertebra posterior edge keep the depth 3 mm is necessary.



405-3001

Impactor

### Instruments

Cat.No.	Description	
421-3501 421-3502 421-3503 421-3504	6mm Nerve Retractor 8mm Nerve Retractor 10mm Nerve Retractor 12mm Nerve Retractor	
421-1607 421-1608 421-1609 421-1610 421-1611 421-1612 421-1613 421-1614 421-1615 421-1616	7mm Distractor with Shaver 8mm Distractor with Shaver 9mm Distractor with Shaver 10mm Distractor with Shaver 11mm Distractor with Shaver 12mm Distractor with Shaver 13mm Distractor with Shaver 14mm Distractor with Shaver 15mm Distractor with Shaver * 16mm Distractor with Shaver *	
422-0660 422-0661 422-0662 422-0663 422-0664 422-0665 422-0666 422-0667	7mm Lumbar PEEK Trial * 8mm Lumbar PEEK Trial * 9mm Lumbar PEEK Trial 10mm Lumbar PEEK Trial 11mm Lumbar PEEK Trial 13mm Lumbar PEEK Trial 14mm Lumbar PEEK Trial	
406-0101	T-Handle	
428-4001	Slide Hammer *	
428-4002	Slide Hammer	
428-4003	Strike Cover	
422-1701	Lumbar PEEK Insertor	

\*Option

Cat.No.	Description	
422-3203	X'Plo Bone Graft Template	•
422-3003	Bone Graft Impactor	
405-3001	Impactor	
99900-034	X`plo Case	
99902-034	X'Plo Instrument Case, Plasty Lid *	
		*Option

## Implants

### Polymer Lumbar Disc Spacer

### Specifications

A	Item Numbar	H / mm	L/mm
5°	594-07056	H=7	
	594-08056	H=8	
	594-09056	H=9	
	594-10056	H=10	24
	594-11056	H=11	24
	594-12056	H=12	
	594-13056	H=13	
	594-14056	H=14	
10°	594-09106	H=9	
	594-10106	H=10	
	594-11106	H=11	24
	594-12106	H=12	
	594-13106	H=13	
	594-14106	H=14	





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