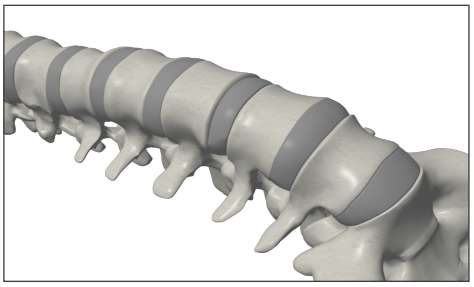
Combo®

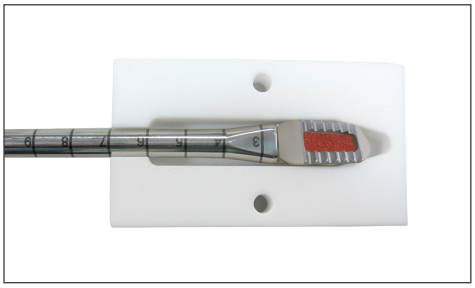
Lumbar Disc Cage

Utilizes The Advantages Of
Titanium & PEEK In One Implant

A-SPINE

Contents





Introduction

The posterior 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' s symptom and maintain the body stabilization immediately, improve the success rate of the bone healing and fusion.

Design Features

1. Combo® Lumbar cage is utilized the titanium and PEEK materials in one implant.
2. Titanium surface is specially treated and it' s bio-active contact surface creates a positive environment of bone healing process.
3. Easy to verify the implant placements by X-ray.
4. The elastic modulus of PEEK is similar to vertebra can reduce the stress shielding.
5. Two of the materials are combined by simple mechanism.
6. Titanium increase bone contact surface topography and initial stability.

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 approach for lumbar

Contraindications

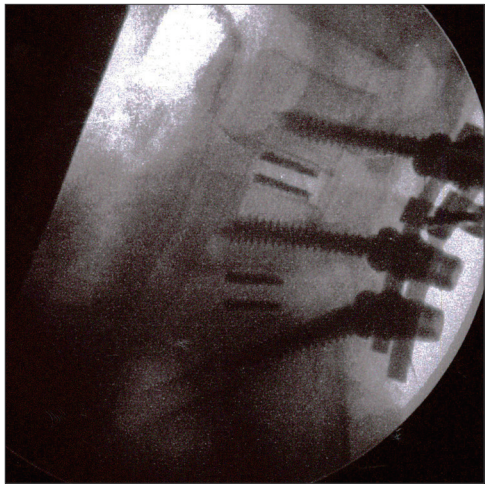
1. Patients with fever or leukocytosis
2. Patients with infections associated with the spine (e.g. spondylodiscitis)
3. Patients with a history of material allergy or who tend to react to foreign bodies
4. Patients whose general medical or psychological condition is unfavorable for- or could be worsened 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

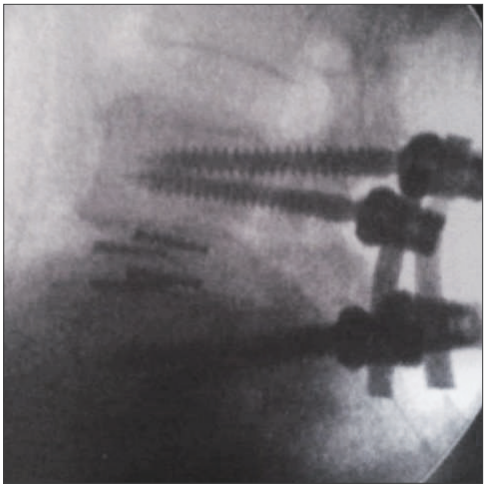
Sterilization

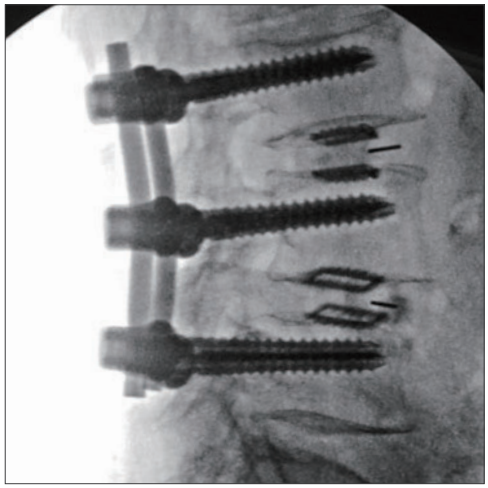
The cage had been sterilized by gamma radiation at least 25 kGy dose.. It should avoid contaminating while operation process. It is necessary to exchange if the packaging has been broken without reason.

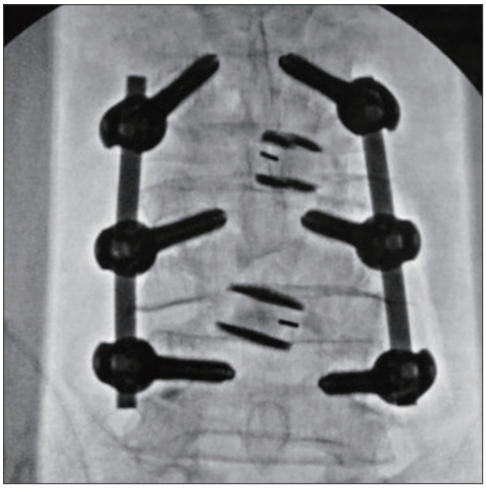
The instruments are provided Non-Sterile to hospital. A-SPINE suggests the device should be sterilized via steam sterilization (under 121 ℃/ 250 ℉, 20 PSIG for 30 mins) to assure SAL (10^{-6}).

Clinical Outcome









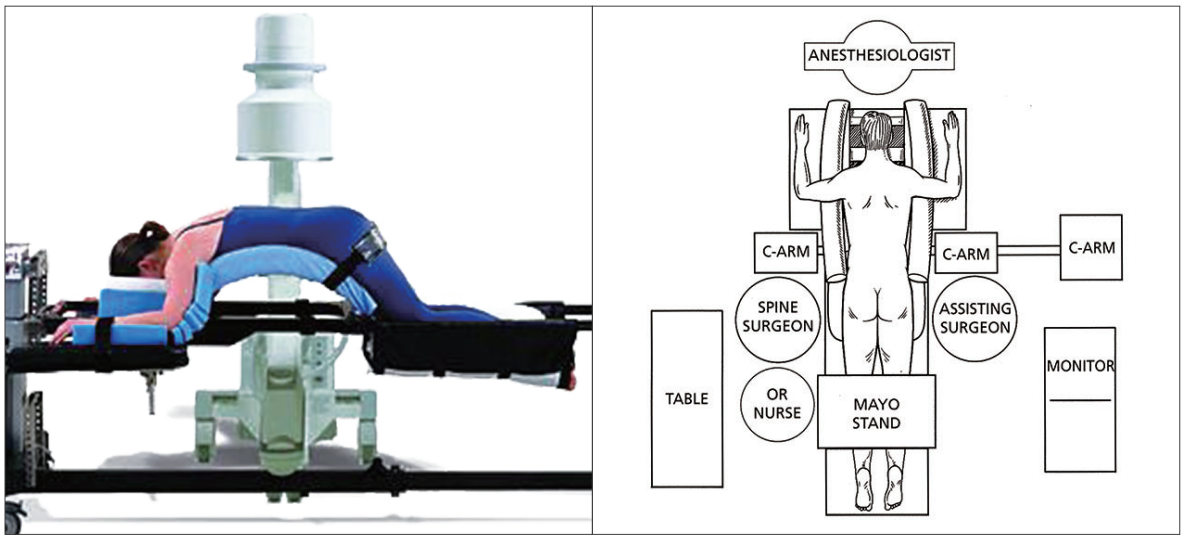
Surgical Technique

Preoperative preparation

Preoperative CT/MRI images are used to confirm lumbar location, vertebrae dimensions, as well as the appropriate size of the Combo Lumbar Disc Cage for preoperative reference. However, the size of the actual implanted is subject to evaluation by the interface between endplate and the implant.

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 reduce 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

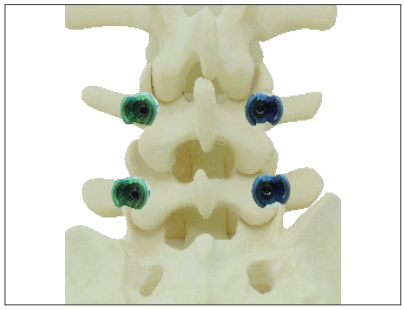
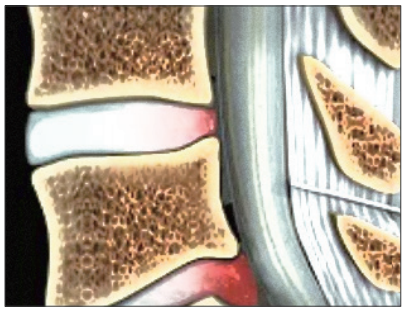


Figure 2



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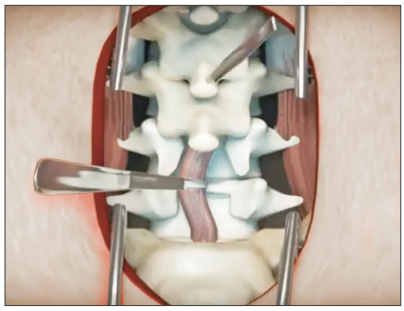


Figure 4

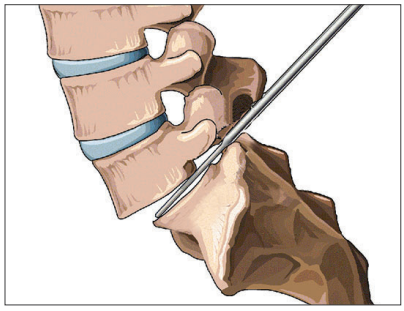


Figure 5

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

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

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 (Fig. 3 & 4)

◆ Step 2

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

Insert the flat side of the 7mm Distractor with Shaver (421-1607) into the affected disc and rotate it 90° to the right or left to restore disc height (Fig. 5).

421-3501~421-3504

6,8,10,12mm
Nerve Retractor

PLIF TLIF

421-1607~421-1614

7-14mm
Distractor with Shaver

PLIF TLIF

406-0101

T-Handle

PLIF TLIF

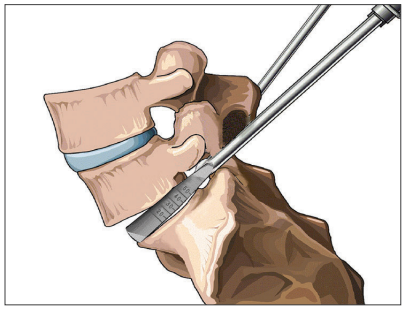


Figure 6

◆ Step 4

Repeat the former procedure with a proper Distractor (421-1607~1614) that insert the larger one and next removed small one until restore the disc height.
C-Arm fluoroscopic imaging is taken and checked for proper disc height restoration (Fig. 6 & Fig. 7).

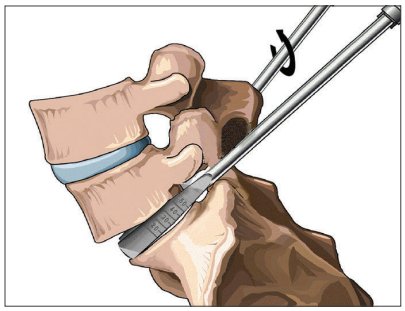


Figure 7

◆ Step 5

Use the Distractor with Shaver or the different kinds of Curette (421-6208 ~ 421-7705) to remove injured disc depending on surgeon preference.

Figure 8

◆ Step 6

If surgeon use 8mm Straight Dens Cup Curette (421-5908) or other instruments to remove the superficial cartilaginous layers of the endplate (Fig. 8).

NOTE:

Be careful not to remove too much subchondral bone for preventing the implant subsidence.

421-6208 / 421-5308

8mm Right / Left Angled Ring Curette

TLIF

421-5608 / 421-6308

8mm Right / Left Angled Cup Curette

TLIF

421-7705

5mm Straight Curette

TLIF

421-5908

8mm Straight Dens Cup Curette

TLIF

Figure 9

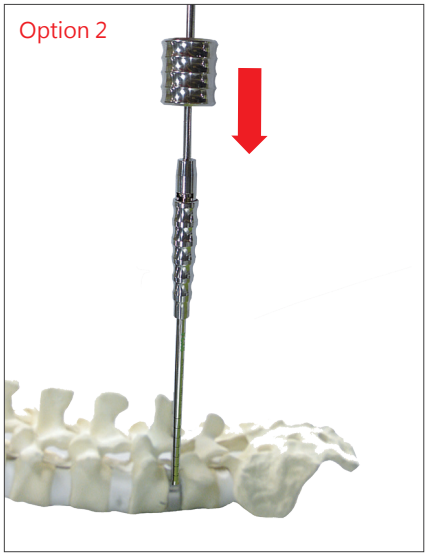


Figure 10

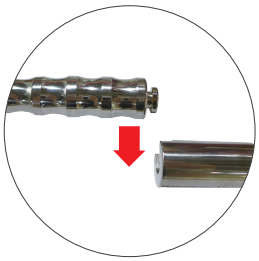
Trial

The Trial from 8mm to 14mm is equivalent to implant size , check the size from small Trial 8mm (422-0661) 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.



Option 1

Use the Strike Cover (428-4003) to buckle the end of Trial and use the Slide Hammer (428-4001) to knock the Trial (Fig. 9).

Option 2

Use Slide Hammer (428-4002) to buckle the end of Trial, and slide the hammer to knock the Trial (Fig. 10).

428-4001

Slide Hammer

PLIF TLIF

428-4002

Slide Hammer

PLIF TLIF

428-4003

Strike Cover

PLIF TLIF

422-0661~422-0667

8~14mm
Lumbar PEEK Trial

PLIF TLIF

Implanting the Combo® Lumbar Cage

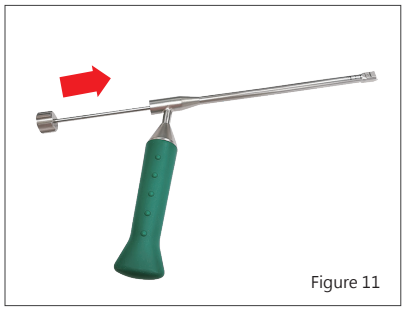


Figure 11

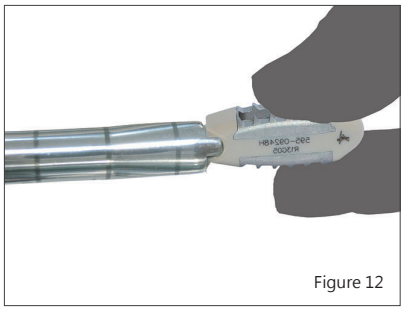


Figure 12

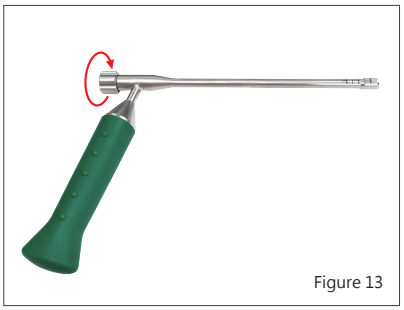


Figure 13

◆ Step 1

Combo® Lumbar Cage implant connect to the Lumbar PEEK Insertor (422-1717) and tighten Inserter axis (422-1718) (Fig. 11 & 12 & 13).

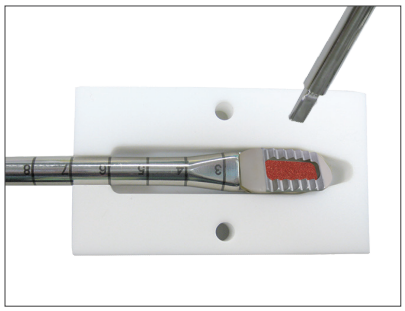


Figure 14

◆ Step 2

Using bone graft, it should be put into the open cavities of the Combo® Lumbar Cage.

The general procedure is putting the Combo® Lumbar Cage into the Bone Graft Template (422-3203) and then fills with the bone graft by Bone Graft Impactor (422-3003) (Fig. 14).

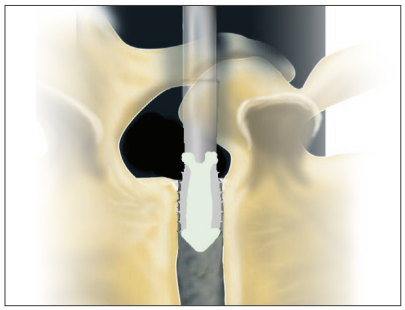


Figure 15

◆ Step 3

Use the Slide Hammer (428-4001) to knock the insertor, and insert the cage slowly.
Hold the inserter firmly and follow the Titanium teeth face to the endplate (Fig. 15).

NOTE:

When insert Combo Cage into the intervertebral disc, avoid twisting or applying lateral force by insertor grip to avoid damage the implant structure.

422-1717

Lumbar PEEK Insertor

PLIF TLIF

422-1718

Inserter axis

PLIF TLIF

422-3203

X' Plo Bone Graft Template

PLIF TLIF

422-3003

Bone Graft Impactor

PLIF TLIF

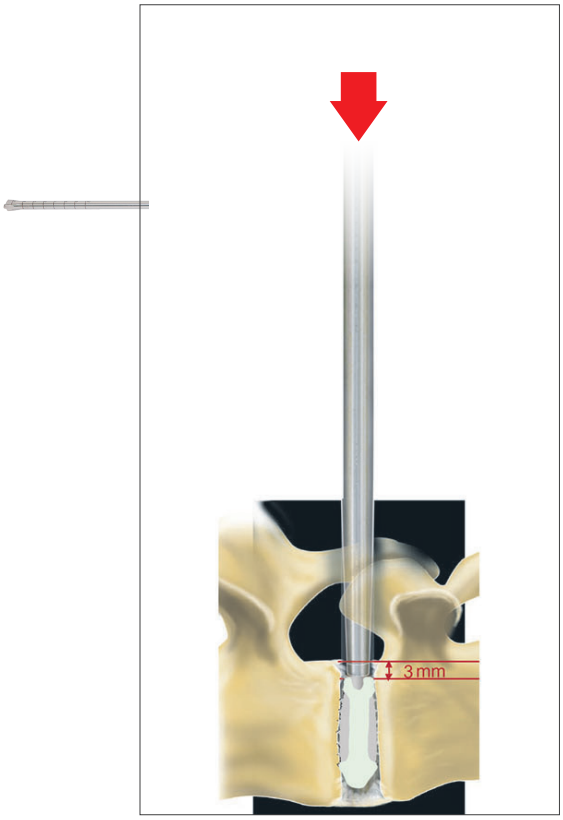


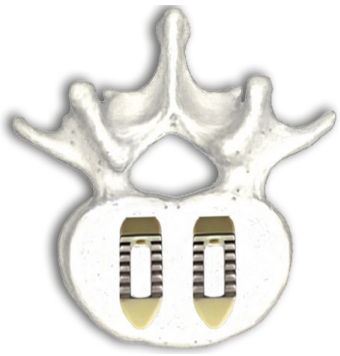
Figure 16

◆ Step 4

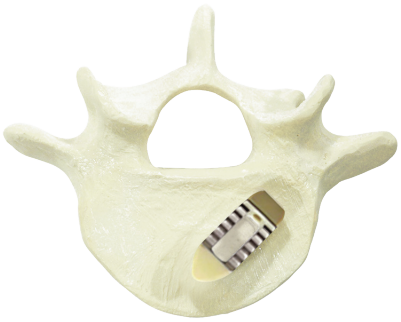
If the position not ready yet, we could use the Impactor (422-3001) to move forward the Combo® Lumbar Cage position (Fig. 16).

NOTE:

Gently impact Combo Lumbar Cage until it is 3mm below the margin of the posterior wall. (PLIF)



PLIF



TLIF

422-3001

Bone Impactor

PLIF TLIF

Instruments PLIF TLIF

Nerve Retractor P T

421-3501	6mm
421-3502	8 mm
421-3503	10 mm
421-3504	12 mm

8mm Right Angled Ring Curette T

421-6208

8mm Left Angled Ring Curette T

421-5308

8mm Right Angled Cup Curette T

421-5608

8mm Left Angled Cup Curette T

421-6308

Distractor with Shaver P T

421-1607	7 mm
421-1608	8 mm
421-1609	9 mm
421-1610	10 mm
421-1611	11 mm
421-1612	12 mm
421-1613	13 mm
421-1614	14 mm
421-1615	15 mm P for optional
421-1616	16 mm P for optional

8mm Angled Rasp T

421-6708

5mm Straight Curette T

421-7705

8mm Straight Dens Cup Curette T

421-5908

T-Handle P T

406-0101

Lumbar PEEK Trial P T

422-0661	8 mm
422-0662	9 mm
422-0663	10 mm
422-0664	11 mm
422-0665	12 mm
422-0666	13 mm
422-0667	14 mm

Inserter axis P T

422-1718

Bone Graft Impactor P T

422-3003

Strike Cover P T

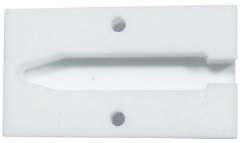
428-4003

Bone Impactor P T

422-3001

Lumbar PEEK Insertor P T

422-1717



X' Plo Bone Graft Template P T

422-3203

Slide Hammer P T

428-4001

Slide Hammer P T

428-4002

X`plo Case

99900-034

X'Plo Instrument Case, Plasty Lid

99902-034

Curette Instrument Set Case (Metal Lid)

99901-038

Curette Instrument Set Case (Plasty Lid)

99903-038

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

Combo® Lumbar Disc Cage (PLIF)

Specifications

A	Item Numbar	H / mm	L / mm
5°	595-08248H	H=8	24
	595-09248H	H=9	
	595-10248H	H=10	
	595-11248H	H=11	
	595-12248H	H=12	
	595-13248H	H=13	
	595-14248H	H=14	

Combo® Lumbar Disc Cage (TLIF)

Specifications

A	Item Numbar	H / mm	L / mm
5°	595-08288H	H=8	28
	595-09288H	H=9	
	595-10288H	H=10	
	595-11288H	H=11	
	595-12288H	H=12	
	595-13288H	H=13	
	595-14288H	H=14	

A-SPINE

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