



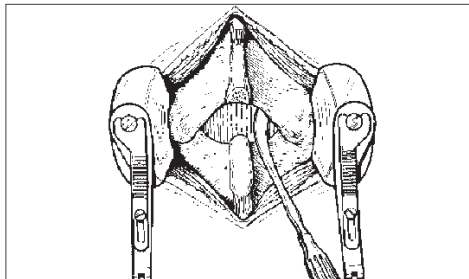
# Rainboo®

Polymer Lumbar Cage

PEEK-OPTIMA®

Invivo®  
biomaterial solutions

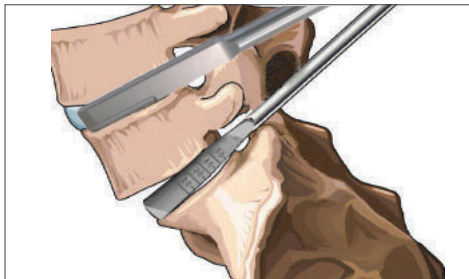
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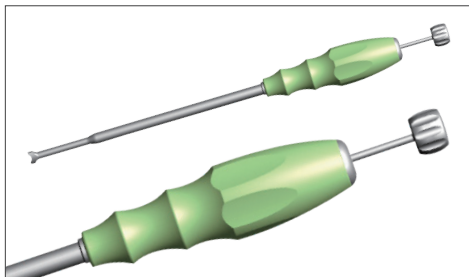
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## Introduction

The new development of spinal surgery is implanting the disc cage; it makes the result become more reliable.

They restore the anatomic and stability from the collapsed discs and also relieve painful pressure on nerves. At last, the device improves the successful rate of the bone healing and fusion.

## Design Rationales

1. Implant is available for transforaminal lumbar interbody fusion, balance avoids overstretching soft tissue.
2. Cage is easily utilized to locate into vertebrae safely by the instruments.

## Advantages

1. High temperature resistance, excellent friction and wear properties over a wide range of pressure, temperature and counterfacial roughness.
2. Bio-compatible.
3. This high performance polymer material is lighter than Titanium alloy, with elastic modulus close to human cancellous bone, making it a better implant material for patients with less occurrence of stress shielding and provide a better fusion quality.
4. Replace the metal material to avoid the sensitivity to metallic implant materials.
5. 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. Pseudarthrosis 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

Rainboo Polymer Lumbar Cage has been sterilized with gamma radiation (SAL 10<sup>-6</sup>) (dose 25 KGy).

## Components

The implant is made of Polyetheretherketone (PEEK) .

## Surgical Technique

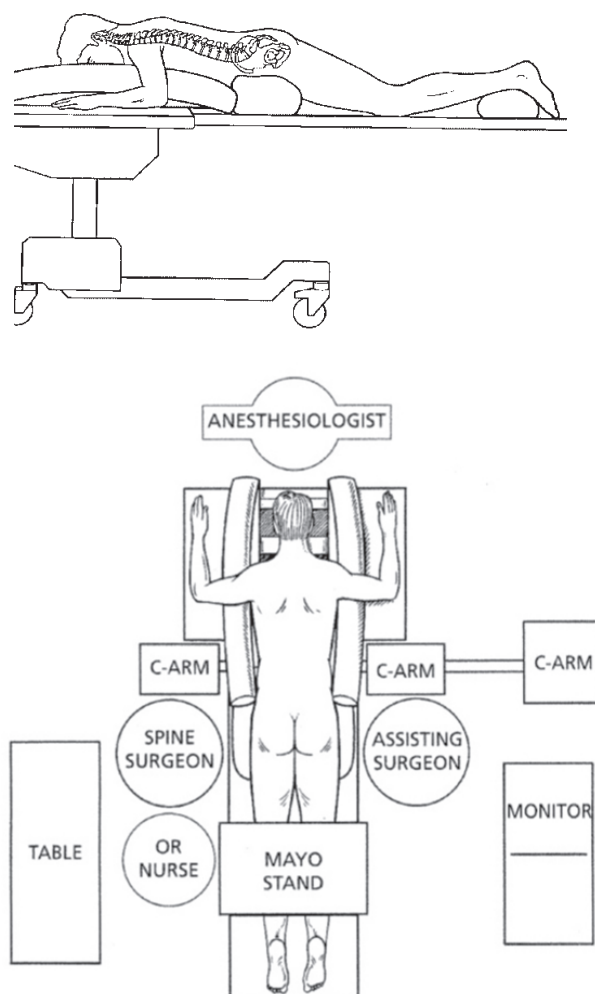
### ○ Preoperative preparation

Preoperative CT/MRI images are used to confirm location, vertebrae dimensions, as well as the appropriate size of the Rainboo Polymer Lumbar Cage for preoperative reference. However, the size of the cage which implanted is subject to evaluation by the Distractor intraoperatively.

### ○ 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 reduction of abdominal compression, minimizing epidural venous bleeding. (Figure 1)

C-arm Fluoroscopic image intensifier is used to supervise throughout the surgery.



Patient position of the posterior lumbar operation

Figure 1



Figure 2

## 01

### Exposure and Preparation of Facet Joints

Placement of pedicle screws.  
(Figure 2)

If need to distract the pedicle screw, use **Pedicle Screw Distractor (407-0903)**  
(Figure 3).

The superior articular process should be resected exposing the disc in the foramen.

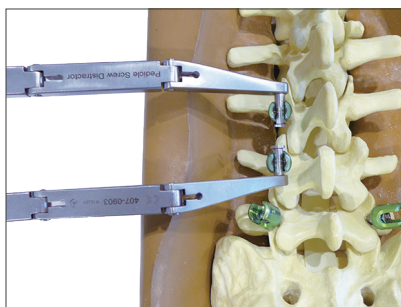


Figure 3

## 02

### Discectomy & Distraction

#### ◆ Step 1

The affected disc is excised in routine manner.

Use the **Nerve Retractor (421-3501 ~ 421-3504)**  
to protect Dura mater.  
(Figure 4 and 5)

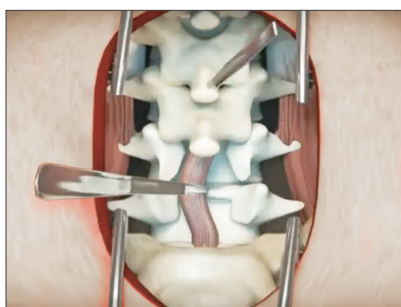


Figure 4

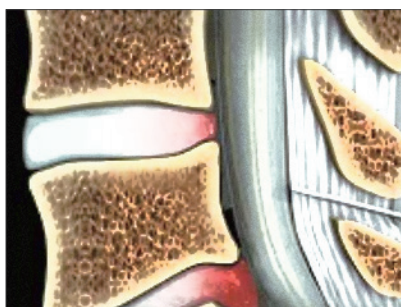


Figure 5



407-0903

Pedicle Screw Distractor  
\*for optional



421-3501~421-3504

Nerve Retractor  
6,8,10,12mm



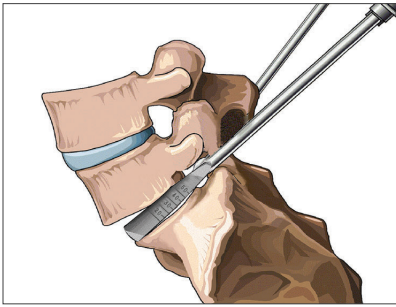


Figure 6

### ◆ Step 2

Use a **T-handle (406-0101)** to connect the Distractor Shaver for operation.(Figure 6)

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.(Figure 7 and 8)

Repeat the former procedure with a proper **Distractor with Shaver (421-1607~1614)** that insert the larger one and next removed small one until restore the disc height.

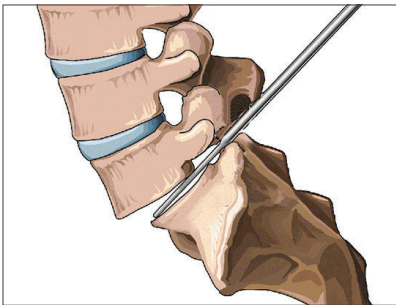


Figure 7



Figure 8



Figure 9

### ◆ Step 3

C-Arm fluoroscopic imaging is taken and checked for proper disc height restoration.

#### NOTE:

1. Distractor with Shaver is used from the smallest, and choose the larger according to the surgical condition.
2. We just want to remove nucleus pulposus. Handling with care, avoiding to hurt the annulus fibrosus about anterior and lateral side.



406-0101

T-Handle



421-1607~421-1614

Distractor With Shaver  
7~14mm

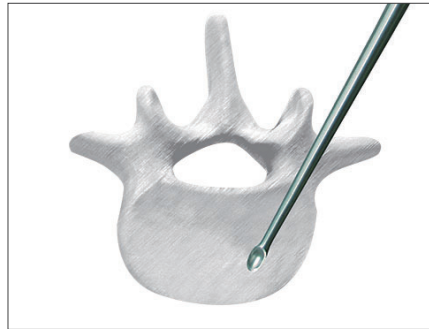
## ◆ Step 4

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

It is recommended to move the **8mm Straight Rasp** (421-6608) to remove the superficial cartilaginous layers of the endplate and expose bleeding cancellous bone. Be careful not to remove too much subchondral bone for preventing the implant subsidence.



421-7707  
7mm Straight Curette (Square)



421-5910  
10mm Straight Dens Cup Curette



421-6208  
8mm Right Angled Ring Curette  
421-5308  
8mm Left Angled Ring Curette



421-6608  
8mm Straight Rasp



421-5608  
8mm Right Angled Cup Curette  
421-6308  
8mm Left Angled Cup Curette

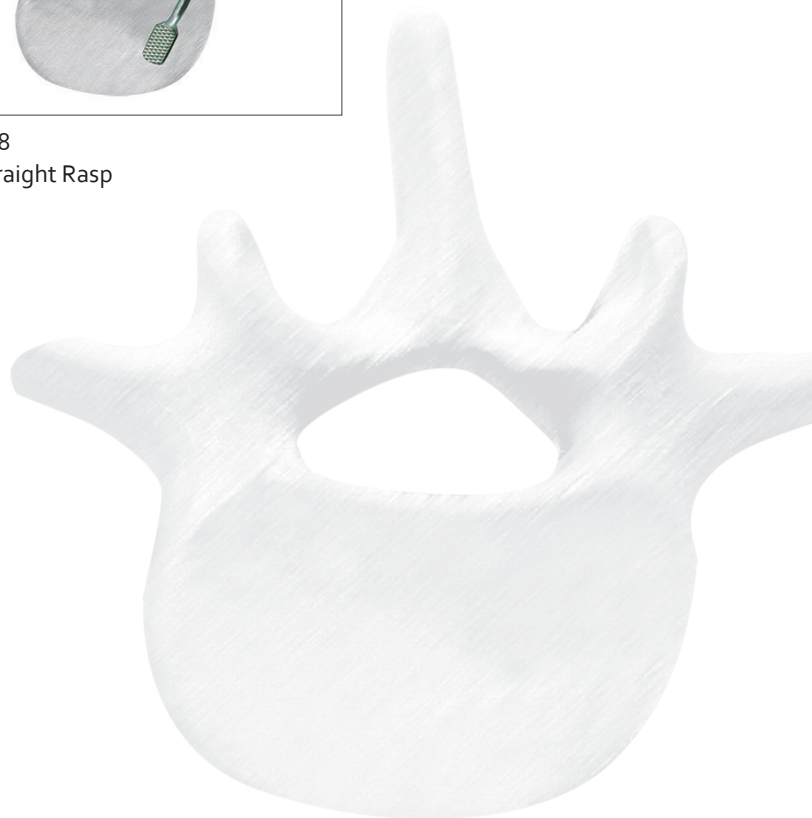


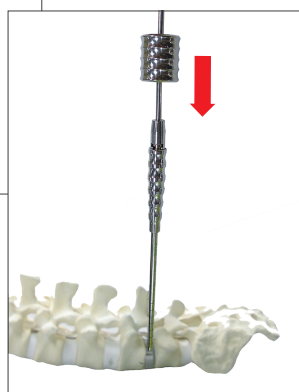




Figure 10



Figure 11



### 03 Exposure and Preparation of Facet Joints

The trial from 7mm to 14mm is equivalent to implant size, check the size from small **Trial (8mm, 421-0602)** to step up size (~ 421-0608). (Figure 10)

#### 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.

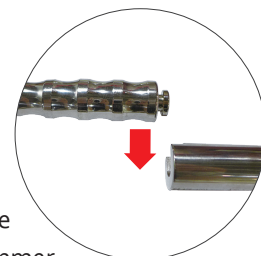
It have two kinds of Slide Hammer.

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)**

(Figure 11)



421-0602~421-0608

Trial  
8~14mm



428-4003

Angled Distractor



428-4001

Slap Hammer



428-4002

Slide Hammer



421-3002

Straight Impactorr

## 04 Implanting the Rainboo Cage

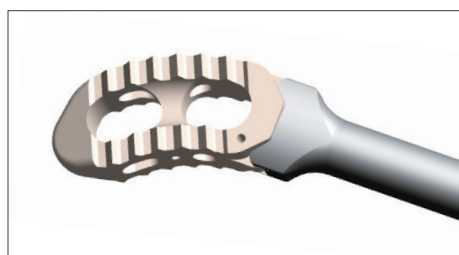
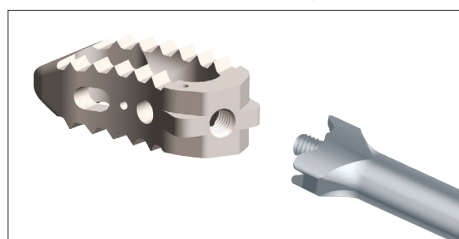
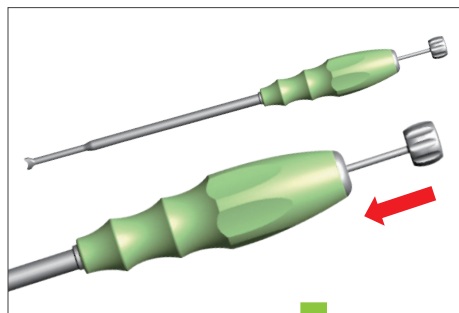


Figure 12

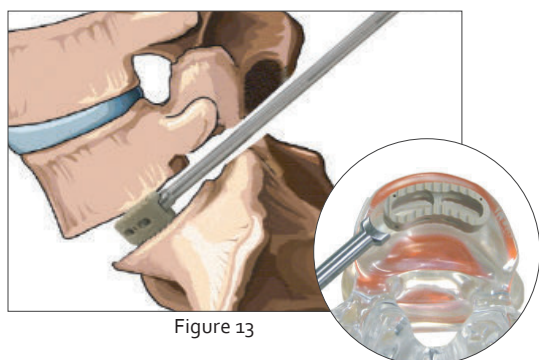


Figure 13

Insert the **Inserter, M3, Inner Pole (421-1704)** into the **Inserter, M3 (421-1703)** for assembly.

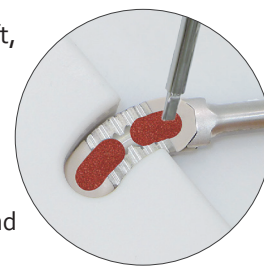
Align the Rainboo Cage with the inserter tip and rotate the inner rod to secure it.

After inserting the Rainboo Cage, inner pole should rotate counterclockwise to remove the inserter.

(Figure 12)

When the spinal fusion need using bone graft, it should be put into the open cavities of the Rainboo Cage.

The general procedure is putting the Cage into the **Bone Graft Template (421-2901)** and then fills with the bone graft by **Bone Graft Impactor (422-3003)**.



### NOTE:

Do not use the Inserter to adjust the cage direction.

Use **Straight Impactor (421-3002)** to adjust the Rainboo Polymer Lumbar Cage just seat in anterior & center disc position. (Figure 13)



## Instrument Set



Instrument Tray 1








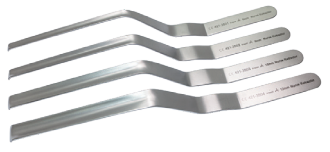


Cat.No.	Description	Q'nty
① 421-1607~421-1614	7~14mm Distractor With Shaver	1
② 421-6208	Right Angled Ring Curette	1
③ 421-5308	Left Angled Ring Curette	1
④ 421-5608	Right Angled Cup Curette	1
⑤ 421-6308	Left Angled Cup Curette	1
⑥ 406-0101	T-Handle	2
⑦ 421-2901	Bone Graft Template	1
⑧ 421-3501~421-3504	6,8,10,12mm Nerve Retractor	1
⑨ 421-6608	8mm Straight Rasp	1
⑩ 421-5910	Straight Cup Curette	1
⑪ 421-7707	7mm Straight Curette	1













Instrument Tray 2

Cat.No.	Description	Q'nty
12 422-0602~422-0608	7~14mm Trial	1
13 421-3002	Straight Impactor	1
14 421-1703	Insertor, M3	1
15 421-1704	Insertor, M3, Inner Pole	1
16 422-3003	Bone Graft Impactor	1
17 428-4001	Slide Hammer	1
18 407-0903	Pediclescrew Distractor	1
19 428-4003	Strike Cover	1
20 428-4002	Slide Hammer	1

## Instruments

Cat.No.	Description	
421-1607 421-1608 421-1609 421-1610 421-1611 421-1612 421-1613 421-1614	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	
421-6208	Right Angled Ring Curette	
421-5308	Left Angled Ring Curette	
421-5608	Right Angled Cup Curette	
421-6308	Left Angled Cup Curette	
406-0101	T-Handle	
421-2901	Bone Graft Template	
421-3501 421-3502 421-3503 421-3504	6mm Nerve Retractor 8mm Nerve Retractor 10mm Nerve Retractor 12mm Nerve Retractor	
421-6608	8mm Straight Rasp	
421-5910	Straight Cup Curette	

Cat.No.	Description	
421-7707	7mm Straight Curette	
421-0601 421-0602 421-0603 421-0604 421-0605 421-0606 421-0607 421-0608	7mm Trial 8mm Trial 9mm Trial 10mm Trial 11mm Trial 12mm Trial 13mm Trial 14mm Trial	
421-3002	Straight Impactor	
421-1704	Insertor, M3, Inner Pole	
421-1703	Insertor, M3	
422-3003	Bone Graft Impactor	
428-4001	Slide Hammer	
407-0903	Pediclescrew Distractor *	
428-4003	Strike Cover	
428-4002	Slide Hammer	



Cat.No.	Description	
99900-038	Rainboo Case with 3 Trays (Metal Lid)	
99902-038	Rainboo Case with 3 Trays (Plasty Lid) *	
99901-038	Rainboo Instrument Case (Metal Lid)	
99903-038	Rainboo Instrument 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

## Rainboo PEEK Lumbar Cage

Cat.No.	Description
598-08266	5° / L26mm / H8mm
598-09266	5° / L26mm / H9mm
598-10266	5° / L26mm / H10mm
598-11266	5° / L26mm / H11mm
598-12266	5° / L26mm / H12mm
598-13266	5° / L26mm / H13mm
598-14266	5° / L26mm / H14mm
598-08326	5° / L32mm / H8mm
598-09326	5° / L32mm / H9mm
598-10326	5° / L32mm / H10mm
598-11326	5° / L32mm / H11mm
598-12326	5° / L32mm / H12mm
598-13326	5° / L32mm / H13mm
598-14326	5° / L32mm / H14mm



## NOTE

## NOTE

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