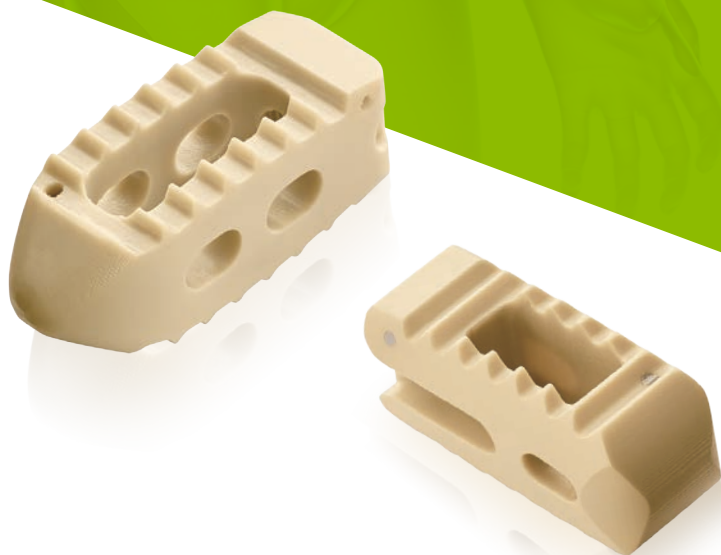




X'PLO®

Polymer Lumbar Cage

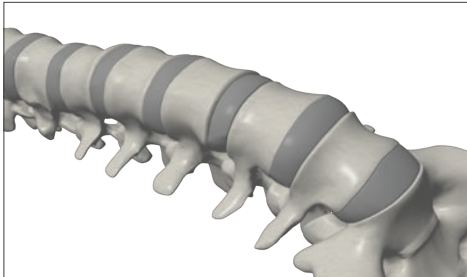


PEEK-**OPTIMA**®

Invibio®
biomaterial solutions

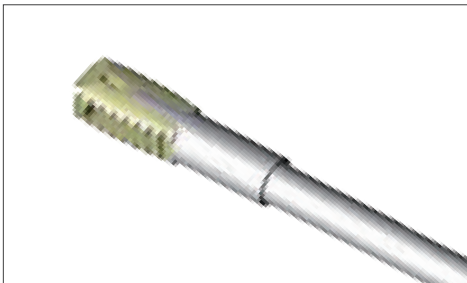
 **A-SPINE**

Contents



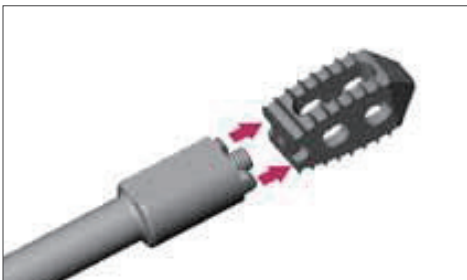
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Introduction

The posterior / anterior spinal fusion surgical techniques have been developed for many years. Numerous types of devices were made and the clinical treatment is good, but the surgical procedures are still very complicated.

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

We design the X'Plo Polymer Lumbar Cage to fit surgeon's need and provide safety and stabilization immediately. They restore the anatomic and stability from the collapsed discs and also relieve painful pressure on nerves. At last, the device improve 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.
3. The zigzagged surfaces can catch the upper & lower vertebrae firmly.

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

1. X'Plo Polymer Lumbar Cage has been sterilized with gamma radiation (SAL 10^{-6})
2. (dose 25 KGy).
When the sterile package is damaged, please return this product to us for exchange or sterilize this product with medical autoclave at 121°C(250°F) 20 PSI for 30 minutes. Once sterilization is complete, this device is ready to use following hospital sterilization protocol.

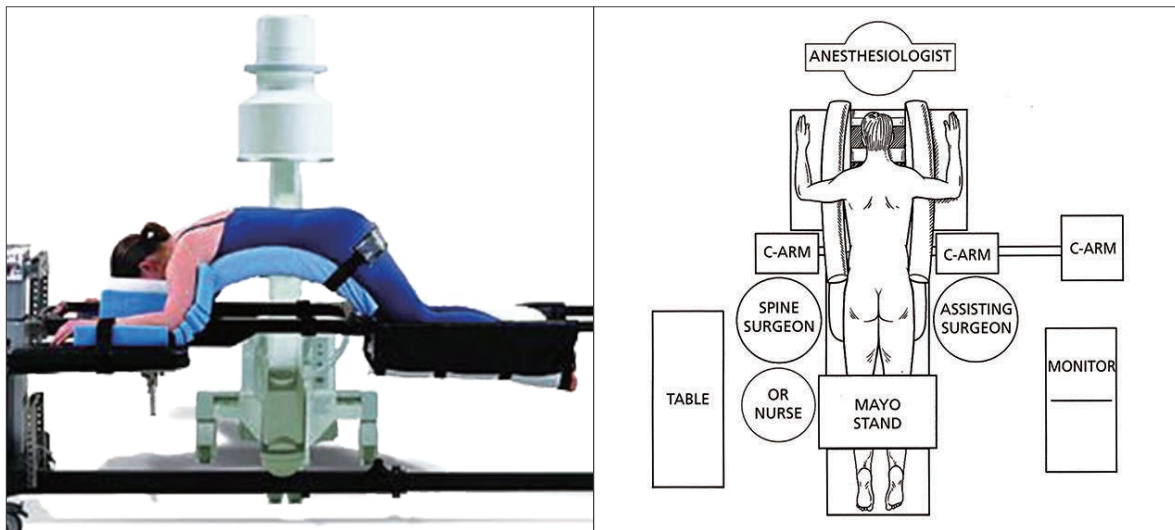
Surgical Technique

◆ 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.

◆ 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. (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

It is recommended that pedicle screws be placed at this time by standard technique. (Fig. 2)

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



Figure 3

♦ 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)

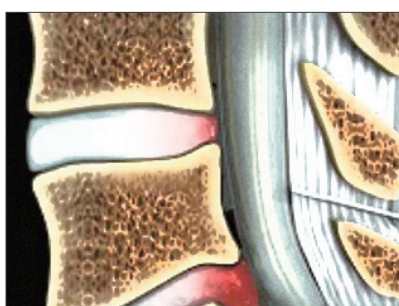


Figure 4

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. (Fig. 4 & 5)

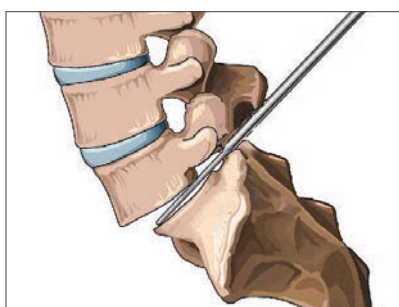


Figure 5



421-3501~421-3504

Nerve Retractor
6,8,10,12mm

N R



421-1607~421-1614

Distractor Shaver
7mm

N R



406-0101

T-Handle

N R

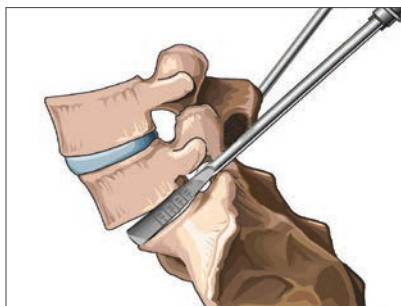


Figure 6

Step 3

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 & 7)

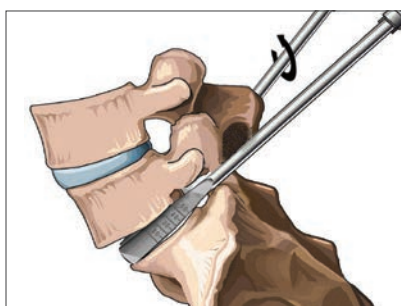


Figure 7

Step 4

Use the Distractor Shaver or the different kinds of **Curette** (**421-6208 ~ 421-7707**) to remove injured disc depending on surgeon preference.



Figure 8

It is recommended to move the **8mm Angled Rasp** (**421-6708**) 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 (Fig. 8 & 9)

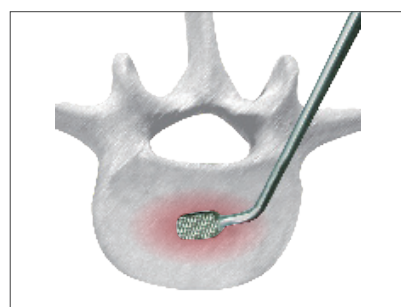


Figure 9



421-5308 / 421-6208

8mm, Left / Right
Angled Ring Curette

N R



421-6308 / 421-5608

8mm, Left / Right
Angled Cup Curette

N R



421-7705 / 421-7707 *

5mm/7mm Straight Curette

N R *option



421-6708

8mm Angled Rasp

N R

Non Rotatable Cage



Figure 10

◆ Trial

The Trial from 7mm to 14mm is equivalent to implant size , check the size from small **8mm Lumbar PEEK Trial (422-0661)** ~**16mm Lumbar PEEK Trial (422-0669)**. (Fig. 10)

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



NOTE

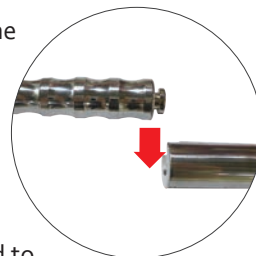
It may result in lordosis and loss stability when Trial is undersized.
However, using an oversized Trial may be difficult to insert or even destroy the vertebral endplate.



Figure 11

It have two kinds of Slide Hammer.

Use the **Strike Cover (428-4003)** to buckle the terminal end of Trial when use the **Slap Hammer (428-4001)** to knock the Trial. (Fig. 11)



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)**



428-4001

Slap Hammer



422-0661~422-0669

8~16mm Lumbar PEEK Trial



428-4003

Strike Cover

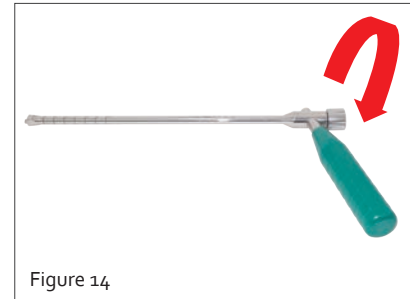
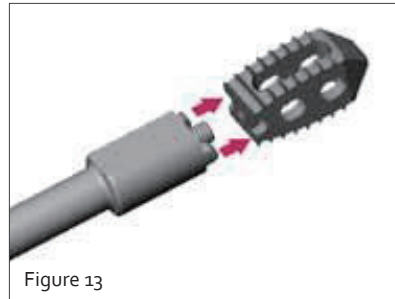
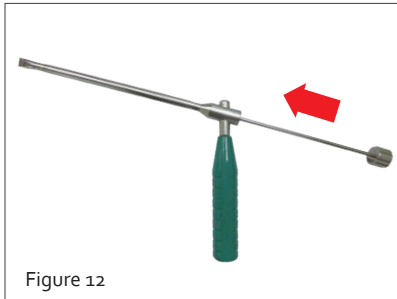


428-4002

Slide Hammer



♦ Implanting the Polymer Lumbar Disc Spacer



The proper size of Polymer Lumbar Disc Spacer implant connect to the top of the **Lumbar PEEK Insertor (422-1717)** and screw tighten by **Insertor Axis (422-1718)** (Figure 12 & 13 & 14).



When the spinal fusion need using bone graft, putting the cage into the **X'Plo Bone Graft Template (422-3203)** and then fills with the bone graft by **Bone Graft Impactor (422-3003)** (Figure 15).



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

Hold the insertor firmly and allow the Ti spacer teeth face to the endplate (Figure 16).



422-1717

Lumbar PEEK Insertor

N



422-1718

Insertor Axis

N



422-3203

X'Plo Bone Graft Template

N



422-3003

Bone Graft Impactor

N R

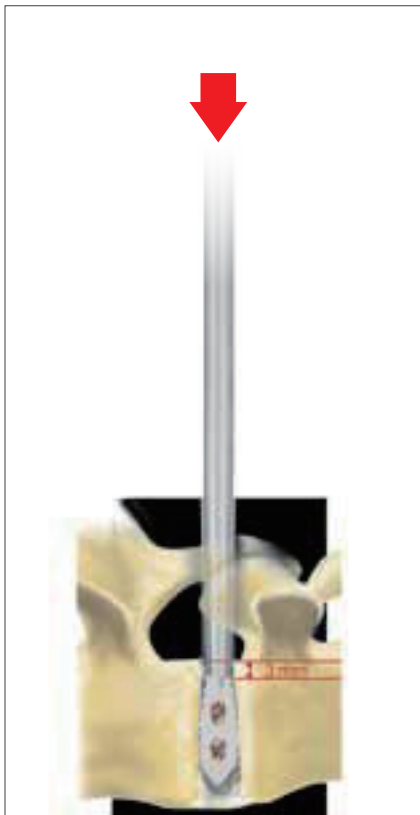


Figure 17

If the position not ready, we could use the **Impactor (422-3001)** to modify the Polymer Lumbar Disc Spacer position and let cage's teeth surface close to the endplate. (Figure 17).



NOTE

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



422-3001

Impactor



Rotatable Cage

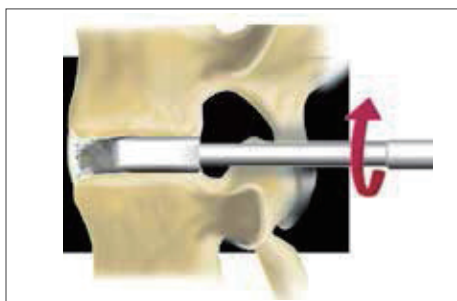


Figure 18



Figure 19



Figure 20

♦ Trial

Assemble **T-handle (406-0101)** and **7mm Lumbar PEEK Trial (422-0630)~16mm Lumbar PEEK Trial (422-0639)**, 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 18).

♦ Implanting the

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 19).

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 Cage.

Put the Cage into the **Bone Graft Template (422-3202)** and then fills with the bone graft by **Bone Graft Impactor (422-3003)** (Figure 20).



422-0631~422-0639

Lumbar PEEK Trial
8~16mm

422-1710

Lumbar PEEK Screw Driver



422-3202

Bone Graft Template



422-3003

Bone Graft Impactor





Figure 21

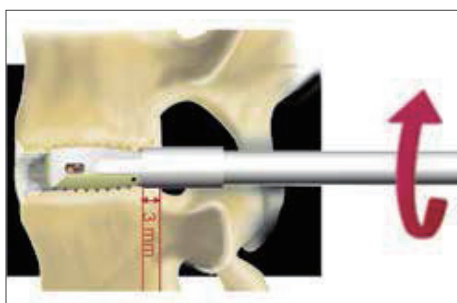


Figure 22

Insert the implant into the disc space within a horizontal direction. **Slide Hammer (428-4001)** can be used for auxiliary insertion (Figure 21). Once the desired depth is achieved, the implant is rotated 90° in order to restore the desired intervertebral height (Figure 22).

Rotate the **Lumbar PEEK Screw Insertor (422-1712, 422-1713)** 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 **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

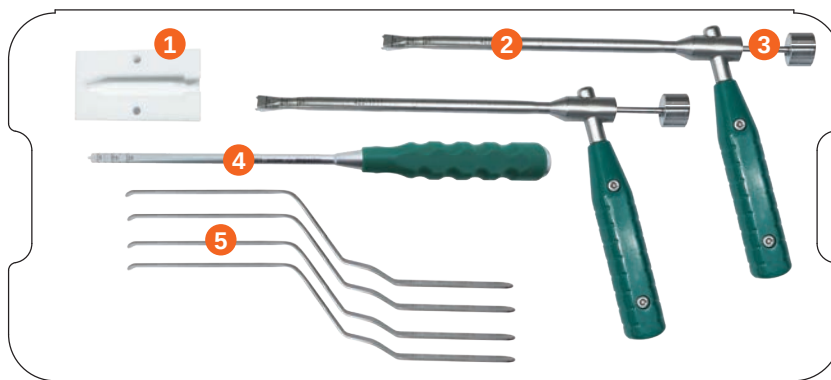


405-3001

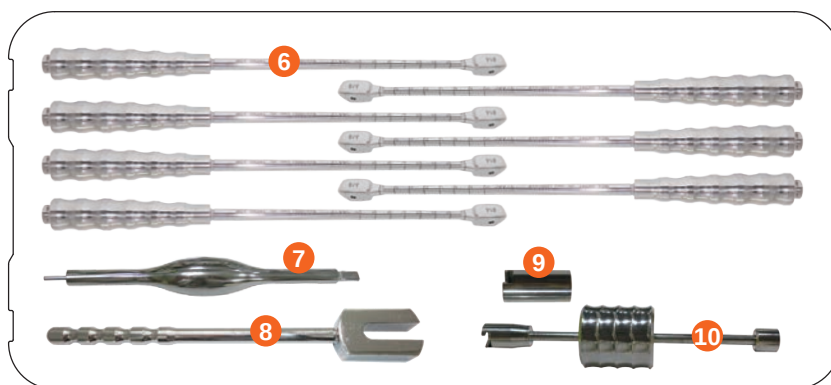
Impactor



Instrument Set N



Instrument Tray 1 (No Rotatable)



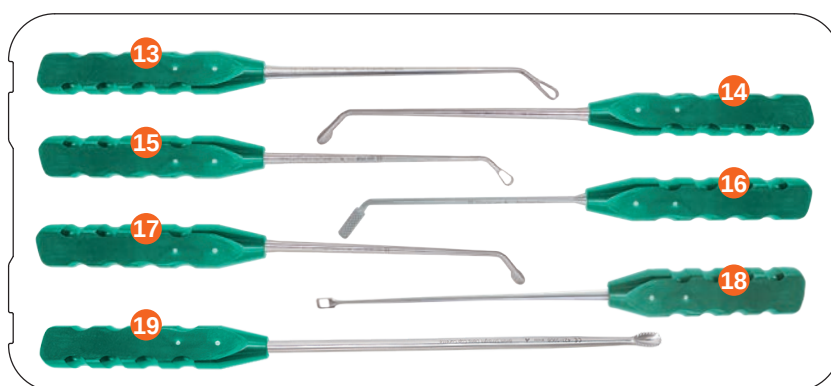
Instrument Tray 2 (No Rotatable)

Cat.No.	Description	Q'nty
① 422-3203	X'Plo Bone Graft Template	1
② 422-1717	Lumbar PEEK Insertor	2
③ 422-1718	Insertor Axis	2
④ 405-3001	Impactor	1
⑤ 421-3501~421-3504	6~12mm Nerve Retractor	4
⑥ 422-0661~422-0667	8~14mm Lumbar PEEK Trial	7
422-0668~422-0669	15-16mm Lumbar PEEK Trial	*
⑦ 422-3003	Bone Graft Impactor	1
⑧ 428-4001	Slide Hammer	*
⑨ 428-4003	Strike Cover	1
⑩ 428-4002	Slide Hammer	1

*option



Instrument Tray 3 (No Rotatable)

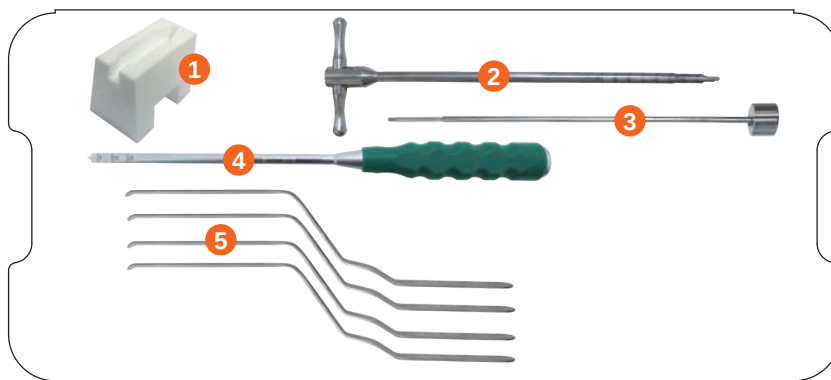


Instrument Tray 4 (No Rotatable)

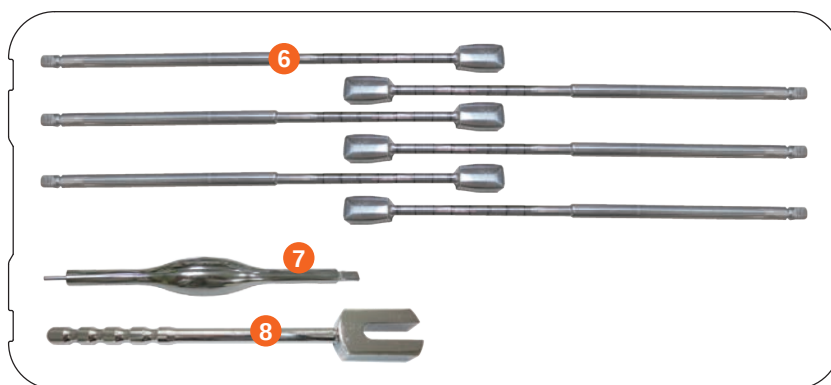
Cat.No.	Description	Q'nty
11 406-0101	T-Handle	2
12 421-1607~421-1614	7~14mm Distractor with Shaver	8
421-1615~421-1616	15,16mm Distractor with Shaver	*
13 421-5308	8mm Left Angled Ring Curette	1
14 42-6308	8mm Left Angled Cup Curette	1
15 421-6208	8mm Right Angled Ring Curette	1
16 421-6708	8mm Angled Rasp	1
17 421-5608	8mm Right Angled Cup Curett	1
18 421-7707	7mm Straight Curette	*
19 421-5908	8mm Straight Dens Cup Curette	1

*option

Instrument Set ^R



Instrument Tray 1 (Rotatable)



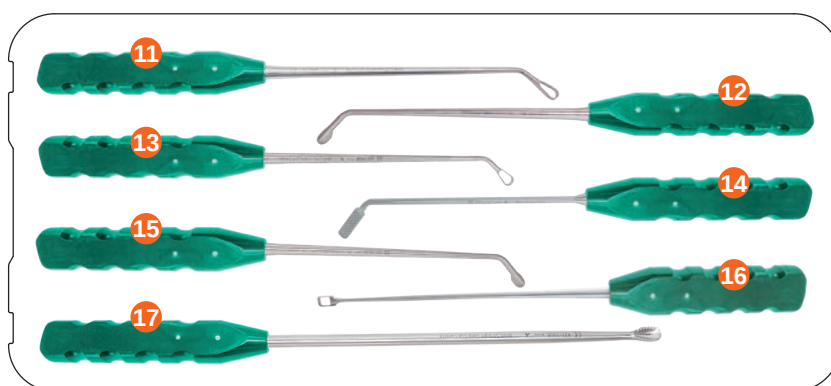
Instrument Tray 2 (Rotatable)

Cat.No.	Description	Q'nty
① 422-3202	Bone Graft Template	1
② 422-1712~422-1713	Lumbar PEEK Insertor	4
③ 422-1710	Lumbar PEEK Screw Driver	4
④ 405-3001	Impactor	1
⑤ 421-3501~421-3504	6~12mm Nerve Retractor	4
⑥ 422-0631~422-0637	8~14mm Lumbar PEEK Trial	7
422-0638~422-0639	15~16mm Lumbar PEEK Trial	*
⑦ 422-3003	Bone Graft Impactor	1
⑧ 428-4001	Slide Hammer	*

*option



Instrument Tray 3 (Rotatable)



Instrument Tray 4 (Rotatable)

Cat.No.	Description	Q'nty
9 406-0101	T-Handle	2
10 421-1607~421-1614	7~14mm Distractor with Shaver	8
421-1615~421-1616	15,16mm Distractor with Shaver	*
11 421-5308	8mm Left Angled Ring Curette	1
12 42-6308	8mm Left Angled Cup Curette	1
13 421-6208	8mm Right Angled Ring Curette	1
14 421-6708	8mm Angled Rasp	1
15 421-5608	8mm Right Angled Cup Curett	1
16 421-7707	7mm Straight Curette	*
17 421-5908	8mm Straight Dens Cup Curette	1

*option

Instruments

Non Rotatable Cage

Rotatable Cage

Cat.No.	Description	
405-3001	Impactor N R	
406-0101	T-Handle N R	
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 N R	
421-3501 421-3502 421-3503 421-3504	6mm 8mm 10mm 12mm Nurve Retractor N R	
421-5308	8mm Left Angled Ring Curette N R	
421-6208	8mm Right Angled Ring Curette N R	
421-6308	8mm Left Angled Cup Curette N R	
421-5608	8mm Right Angled Cup Curett N R	
421-5908	8mm Straight Dens Cup Curette N R	
421-6708	8mm Angled Rasp N R	
421-7705 421-7707	5mm Straight Curette N R 7mm Straight Curette * N R	
422-1710 422-1718	Lumbar PEEK Screw Driver R Insertor Axis N	

*Option

Non Rotatable Cage

Rotatable Cage

Cat.No.	Description	
422-3003	Bone Graft Impactor N R	
428-4001	Slide Hammer * N R	
422-0661 422-0662 422-0663 422-0664 422-0665 422-0666 422-0667 422-0668 422-0669	8mm 9mm 10mm 11mm 12mm 13mm 14mm 15mm * 16mm * Lumbar PEEK Trial N	
422-1717	Lumbar PEEK Insertor N	
422-3203	X'Plo Bone Graft Template N	
428-4002	Slide Hammer N	
428-4003	Strike Cover N	
422-0631 422-0632 422-0633 422-0634 422-0635 422-0636 422-0637 422-0638 422-0639	8mm 9mm 10mm 11mm 12mm 13mm 14mm 15mm * 16mm * Lumbar PEEK Trial R	
422-3202	Bone Graft Template R	

*Option

Rotatable Cage

Cat.No.	Description	
422-1712	4mm Lumbar PEEK Insertor R	
422-1713	6mm Lumbar PEEK Insertor R	
99900-034	X'plo Case* N	
99901-038	Curette Instrument Case N R	
99903-038	Curette Instrument Set Case (Plasty Lid) * N R	

*Option

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

X'Plo PEEK Lumbar Cage(A) N

Cat.No.	Description
590-08266	X'Plo PEEK Lumbar Cage(A) 0° / L 26 x H8 mm
590-09266	X'Plo PEEK Lumbar Cage(A) 0° / L 26 x H9 mm
590-10266	X'Plo PEEK Lumbar Cage(A) 0° / L 26 x H10 mm
590-11266	X'Plo PEEK Lumbar Cage(A) 0° / L 26 x H11 mm
590-12266	X'Plo PEEK Lumbar Cage(A) 0° / L 26 x H12 mm
590-13266	X'Plo PEEK Lumbar Cage(A) 0° / L 26 x H13 mm
590-14266	X'Plo PEEK Lumbar Cage(A) 0° / L 26 x H14 mm



X'Plo PEEK Lumbar Cage(B) N

Cat.No.	Description
595-08266	X'Plo PEEK Lumbar Cage(B) 5° / L 26 x H8 mm
595-09266	X'Plo PEEK Lumbar Cage(B) 5° / L 26 x H9 mm
595-10266	X'Plo PEEK Lumbar Cage(B) 5° / L 26 x H10 mm
595-11266	X'Plo PEEK Lumbar Cage(B) 5° / L 26 x H11 mm
595-12266	X'Plo PEEK Lumbar Cage(B) 5° / L 26 x H12 mm
595-13266	X'Plo PEEK Lumbar Cage(B) 5° / L 26 x H13 mm
595-14266	X'Plo PEEK Lumbar Cage(B) 5° / L 26 x H14 mm



X'Plo PEEK Lumbar Cage(A) N

Cat.No.	Description
590-08306	X'Plo PEEK Lumbar Cage(A) 0° / L 30 x H8 mm
590-09306	X'Plo PEEK Lumbar Cage(A) 0° / L 30 x H9 mm
590-10306	X'Plo PEEK Lumbar Cage(A) 0° / L 30 x H10 mm
590-11306	X'Plo PEEK Lumbar Cage(A) 0° / L 30 x H11 mm
590-12306	X'Plo PEEK Lumbar Cage(A) 0° / L 30 x H12 mm
590-13306	X'Plo PEEK Lumbar Cage(A) 0° / L 30 x H13 mm
590-14306	X'Plo PEEK Lumbar Cage(A) 0° / L 30 x H14 mm



X'Plo PEEK Lumbar Cage(B) N

Cat.No.	Description
595-08306	X'Plo PEEK Lumbar Cage(B) 5° / L 30 x H8 mm
595-09306	X'Plo PEEK Lumbar Cage(B) 5° / L 30 x H9 mm
595-10306	X'Plo PEEK Lumbar Cage(B) 5° / L 30 x H10 mm
595-11306	X'Plo PEEK Lumbar Cage(B) 5° / L 30 x H11 mm
595-12306	X'Plo PEEK Lumbar Cage(B) 5° / L 30 x H12 mm
595-13306	X'Plo PEEK Lumbar Cage(B) 5° / L 30 x H13 mm
595-14306	X'Plo PEEK Lumbar Cage(B) 5° / L 30 x H14 mm

X'Plo PEEK Lumbar Cage(D) Rotatable PEEK R

Cat.No.	Description
589-08266	X'Plo PEEK Lumbar Cage (D) (Rotatable PEEK) 5° / L 26 x W6 x H8 mm
589-09266	X'Plo PEEK Lumbar Cage (D) (Rotatable PEEK) 5° / L 26 x W6 x H9 mm
589-10266	X'Plo PEEK Lumbar Cage (D) (Rotatable PEEK) 5° / L 26 x W6 x H10 mm
589-11266	X'Plo PEEK Lumbar Cage (D) (Rotatable PEEK) 5° / L 26 x W6 x H11 mm
589-12266	X'Plo PEEK Lumbar Cage (D) (Rotatable PEEK) 5° / L 26 x W6 x H12 mm
589-13266	X'Plo PEEK Lumbar Cage (D) (Rotatable PEEK) 5° / L 26 x W6 x H13 mm
589-14266	X'Plo PEEK Lumbar Cage (D) (Rotatable PEEK) 5° / L 26 x W6 x H14 mm



Note



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