



Combo[®]

Cervical Disc Cage



Utilizes The Advantages Of
Titanium & PEEK In One Implant

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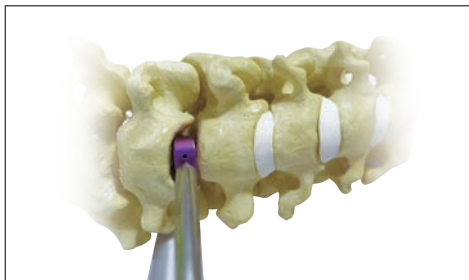
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Introduction

The anterior spinal fusion surgical techniques have been developed for many years, and numerous types of instruments being made with significant improvement of the clinical treatment. The state-of-the-art development of spinal implant is cage has capability of enhancing the bony fusion and avoids subsidence.

This device eliminates or reduces patient's symptom and promote long term stability of the implant, through the successful fusion of the lesion site and adjacent vertebrae of the cervical spine by the design and material.

Design Features

1. The Combo® Cervical Disc Cage is a trapezoid shape implant with superior oval build up.
2. Titanium surface is specially treated and it bio-active contact surface creates a positive environment of bone healing process.
3. The elastic modulus of PEEK is similar to vertebra can reduce the stress shielding.
4. The Combo® Cervical Disc Cage combine surgical PEEK and Ti6Al4V alloy by a simple mechanism.
5. Easy to verify the implant placements by X-ray.
6. Keels increase bone contact surface topography and initial stability.
7. Provide two large spaces for bone graft.

Indications

Indications for fusion procedures are for example:

1. Degenerative disk disease
2. Spondylolisthesis and retrolisthesis grade 1
3. Degenerative scoliosis
4. Revision operation
5. Pseudarthrosis

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

Possible Adverse Effects

The following are specific adverse effects which should be understood by the surgeon and explained to the patient. These do not include all adverse effects which can occur with surgery in general, but are important considerations particular to polymer internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

1. Dural leak.
2. Nerve damage due to surgical trauma.
3. Infection.
4. Pain, discomfort or abnormal sensations due to presence of the device.
5. Allergic and foreign Body Reactions.
6. Bending or fracture of the implant; loosening of the implant.
7. Delayed union or nonunion
8. Decrease in bone density due to stress shielding.
9. Bursitis.

Sterilization

1. Combo® Cervical Disc Cage can be sterilized with gamma radiation (SAL 10⁻⁶) (dose 25 KGy).
2. If the sterile package is damaged, please return the product for exchange.

Surgical Technique

○ Preoperative Preparation

CT or MRI is employed to confirm the location of lesion, dimensions of the vertebra(e) to be fused, to determine the lengths of plate & screws to be implanted.
Operation is performed under endo-tracheal anesthesia.

○ Patient Position

The patient is placed in a supine position. (Figure 1)
Patient's neck is positioned with a rolled-up towel & pad between the scapulae to keep the operated site slightly overextended if desired.
The head is kept in neutral position and is rotated 15° to 30° to the opposite side.
Both shoulders were pulled downward with strips of adhesive tape to obtain clear Access of radiographic visualization of lower cervical spine.

NOTE:

Care should be taken to avoid overstretching the brachial plexus.

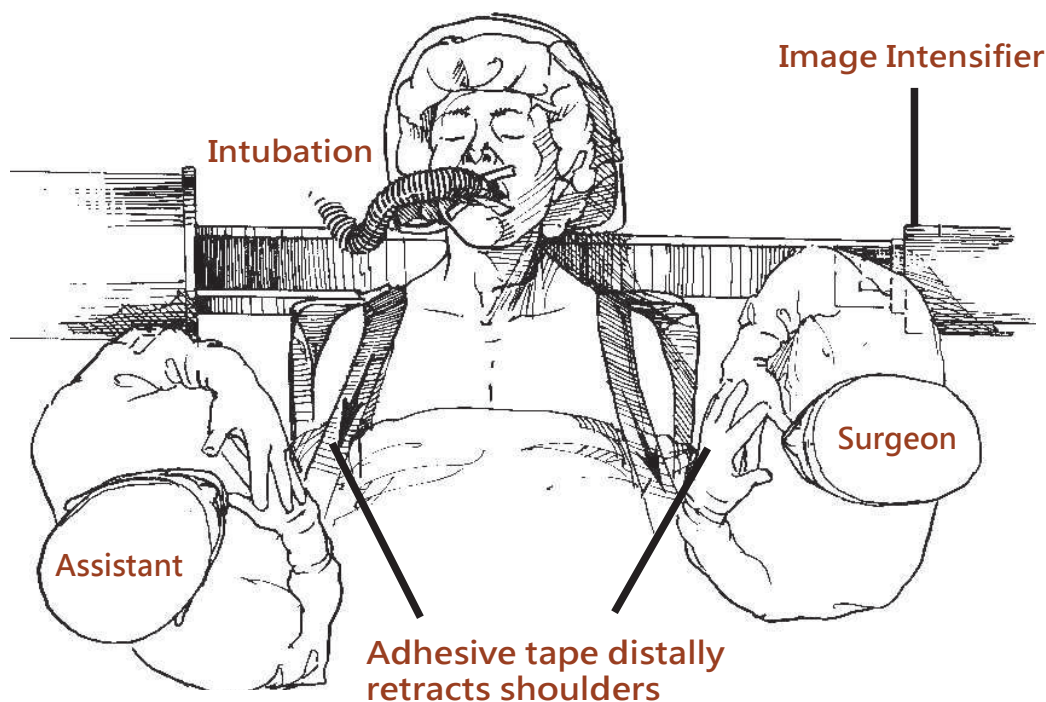


Figure 1

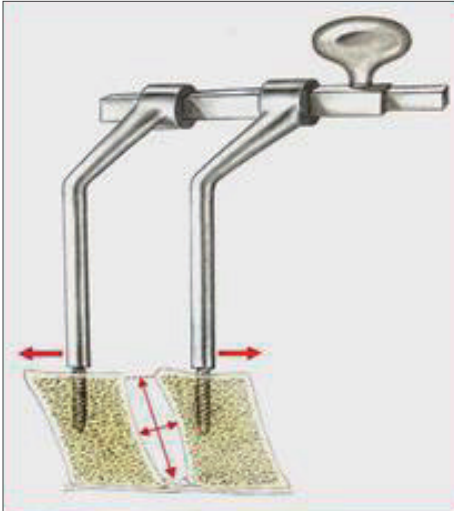


Figure 5

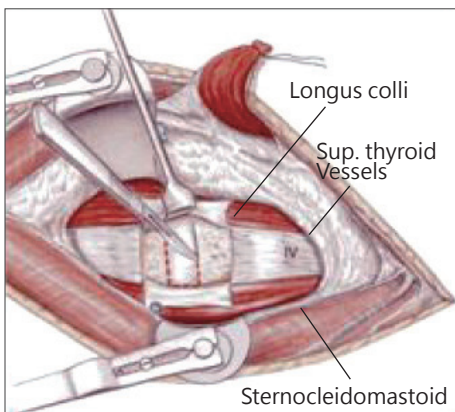


Figure 6

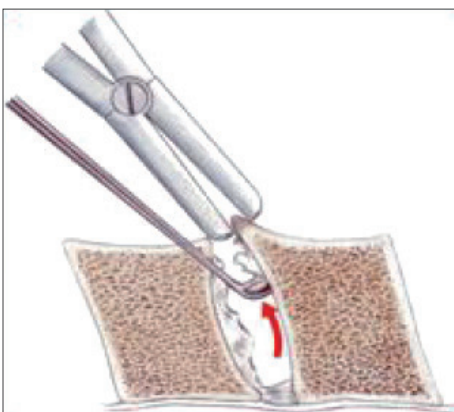


Figure 7

○ Discectomy

◆ Step 1

The lesioned segment(s) is confirmed with C-arm.

◆ Step 2

The longus colli muscle is retracted laterally with a self-retaining retractor while Caspar Distractor is applied longitudinally distracting the upper and lower bodies.

The anterior longitudinal ligament and anterior portion of the annulus fibrosus are excised, exposing vertebral body. (Fig. 6)

◆ Step 3

The upper and lower end plates of the adjacent vertebrae are removed. Large anterior osteophytes are trimmed, yet the original cortical edge is retained. (Fig.7)

◆ Step 4

If the end plates are highly sclerotic and avascular, perforation at individual spots with a ball-pointed drill is carried out with an prepared bone bed surface averaged 15mm X 15mm.



Figure 6

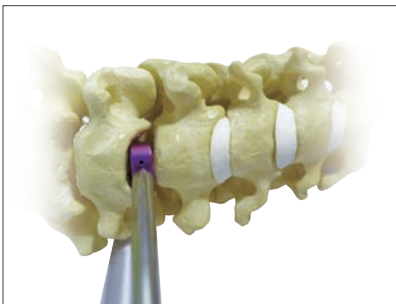


Figure 7

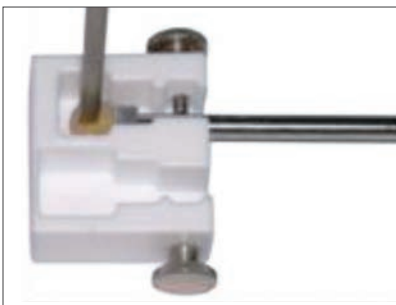


Figure 8

○ Trialing & Implanting

◆ Step 1

After remove the remaining injured disc, use the 6 mm Implant Driver (218-0806) to screw tightening the Trial (232-0665~232-0670) inserting & pushing into the space properly.

The trials are used from the smallest and choose the larger according the surgical condition.

◆ Step 2

Choose a proper implant onto the top of the Cervical PEEK Insertor (Straight) (232-1702) and screw Cervical PEEK Screw Driver (232-1704) tightened.

◆ Step 3

Put the cage into the bone graft template, and fill bone graft into cage by using Bone Graft Impactor (218-3301).

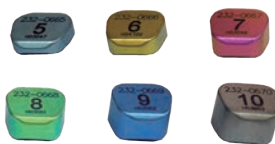
◆ Step 4

Remove the Trial and insert the implant into the space, radiographic imaging will verify implant positioning then removed the Implant Driver.

Combo® Cervical Implants Specification



·Width: 14 / 15mm
·Height: 5~10mm
·Length: 12 / 14mm



232-0665~232-0670
5~10mm Trial



218-0806

6mm Implant Driver



232-1702

Cervical PEEK Insertor
(Straight)



232-1704

Cervical PEEK Screw Driver



232-2901

Bone Graft Block

General Warnings

The above description is only the standard installing procedure of the Combo® Cervical Disc Cage. Since every patient's physiological condition is different, the surgeon should take detail examination and careful judgment before surgery, so that the operation will go through smoothly and the patient may also recover earlier.

A Postoperative Management

Wound Closure

1. A drain is introduced, and the wound is closed by suturing the platysma and skin.
2. The wound is subsequently closed in the routine manner.

Postoperative Management

1. The patient is allowed to move on the next day postoperatively.
2. Drain is removed 48 hours post-operatively.
3. Patients should be instructed to wear a soft plastic form cervical collar for six weeks following surgery.

B Instructions for Patient

1. The patient must be aware of all postoperative restrictions, particularly limitations related to occupational and sports activities .
2. The patient should be warned that non-compliance with the postoperative instructions may lead to failure of the implant. Additional surgery may also be required to remove the device.

C Precautions to Surgeons

1. The implant should not be used to span more than 3 segments.
2. The surgeons must be thoroughly knowledgeable of the mechanical and material limitations of polymer surgical implants.
3. The patient should be adequately instructed . Postoperatively care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing . The patient must be made aware of the imitations of the implant, and that physical activity and full weight bearing have been implicated in premature failure of polymer internal fixation devices. The patient should be made aware that a polymer implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An overactive, debilitated or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.

4. Removal of the implant after healing: polymer implants can be loosen, fracture, corrode, migrate, possibly increase the risk of infection, cause pain or stress shield bone even after healing, particular in young, active patients. The surgeons should carefully weigh the risks versus benefits when deciding whether to remove the implant. Implant removal should be followed by adequate postoperative management to avoid re-fracture. If the patient is older and has a low active level, the surgeon may choose not to remove the implant, thus eliminating the risks involved with a second surgery.
5. Until firm bony union (confirmed by clinical and radiographic examination) is established, the patient should employ adequate external support and restrict physical activities which would place excessive stresses upon the implant or allow movement and delay or prevent healing.

D Precautions to Patients

1. Although the use of internal fixation implants has given the surgeons a means of bone fixation and help generally in the management of fracture and reconstructive surgery, these implants are only intended to be a temporary device to assist normal healing and are not intended to replace normal body structures. Polymer bone fixation devices are internal splints which provide a means of bone fixation while normal bone healing occurs.
2. Postoperative care is extremely important. The patient must be instructed in the limitations of this implant and must be warned regarding weight-bearing and body stress on the device prior to firm bone healing. The patient should be warned that non-compliance with postoperative instructions could lead to failure of the device and the possible need thereafter for additional surgery to remove the device.

E Warnings

1. The activity is not as well as the natural spine. No implant could bear the load of the body with no resistance to stress for a long period.
2. The implant does not have the same resistance as the normal, healthy spine. So we cannot forecast the implant could bear the load of the body in no other circumstances condition.
3. The Implant may collapse under a heavy load and interrupt the bone healing over. The implant would share the loading only after the bone fusion. If the load occurs before the fusion, it probably causes fatigue fracture.
4. The Implant could never be reused. A removed implant cannot be implanted into human body again.

Instruments



6mm Implant Driver

218-0806



Cervical PEEK Insertor
(Straight)

232-1702



Cervical PEEK Screw Driver

232-1704



Cervical trial Block

20151-005

*for optional



Trial

232-0665	5 mm
232-0666	6 mm
232-0667	7 mm
232-0668	8 mm
232-0669	9 mm
232-0670	10 mm



Bone Graft Block

232-2901



Bone Graft Impactor

218-3301



Cervical PEEK Case(Metal Lid)

99901-005



Cervical PEEK Case(Plasty Lid)

99903-005

*for optional

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/>

NOTE:

For complete listing of sizes and catalog numbers for its implants and instruments, please refer to its Catalog.

Implants

Combo® Cervical Disc Cage

Specifications

Item Number	H / mm	L / mm	W / mm	Angulation
165-25128H	H=5	12	14	5°
165-26128H	H=6			
165-27128H	H=7			
165-28128H	H=8			
165-29128H	H=9			
165-20128H	H=10			
165-25148H	H=5	14	15	
165-26148H	H=6			
165-27148H	H=7			
165-28148H	H=8			
165-29148H	H=9			
165-20148H	H=10			





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