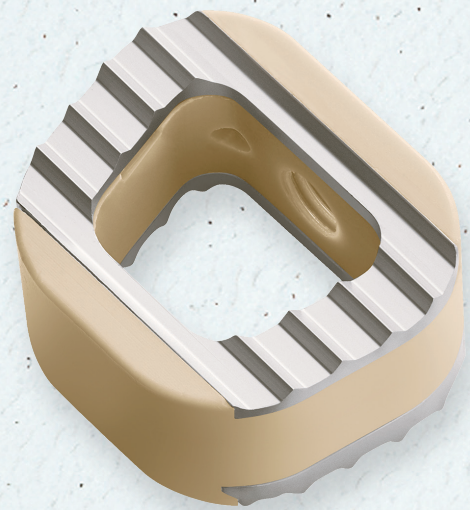
A-SPINE

Combo®
Cervical Disc Cage

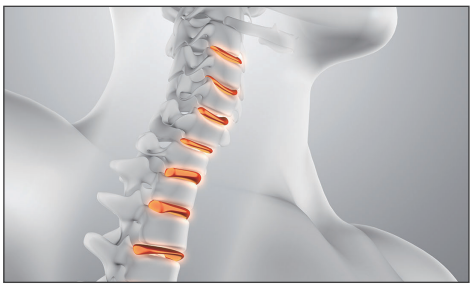


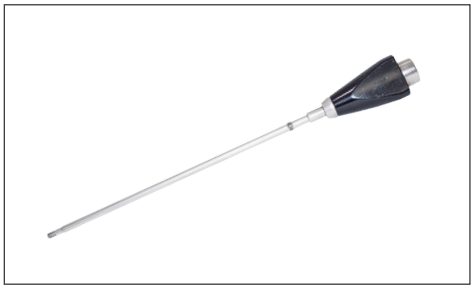
Characteristics

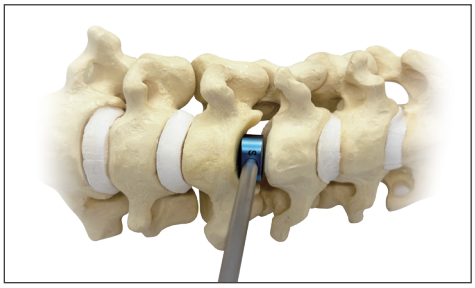
- Combo utilizes the advantages of Titanium & PEEK in one implant
- Encouraging rapid bony ingrowth and increasing fusion rate
- Optimizing intervertebral stability
- Excellent visualization on postoperative CT & MRI scan

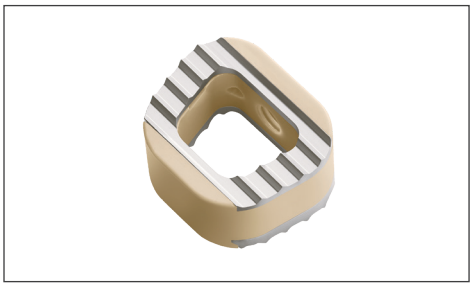
Advancing Spine Technology

Contents









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 Titanium alloy (Ti6Al4V) 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 large spaces for bone graft

Indications

1. Degenerative disc 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

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.

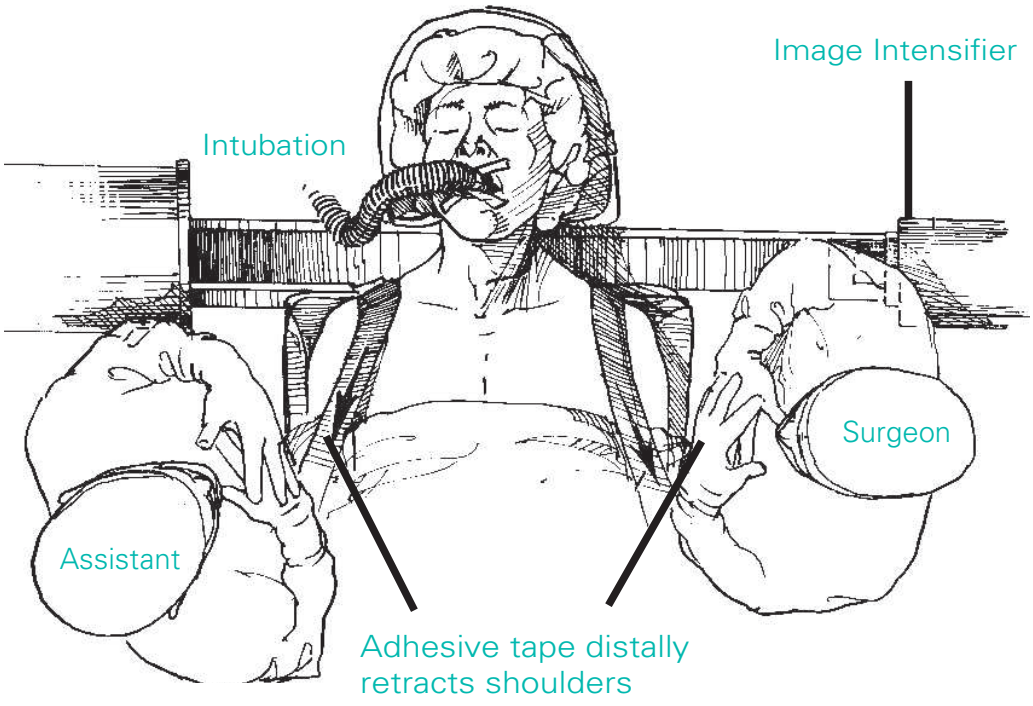


Figure 1

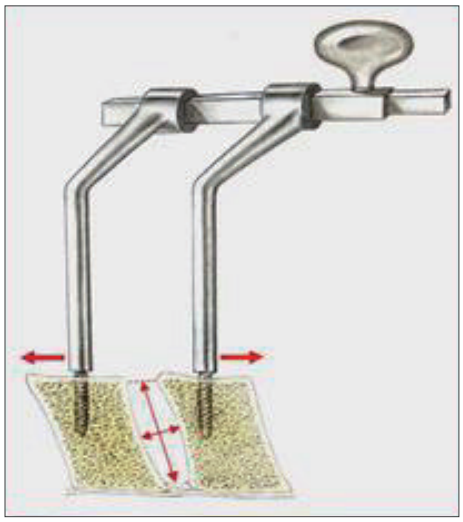


Figure 5

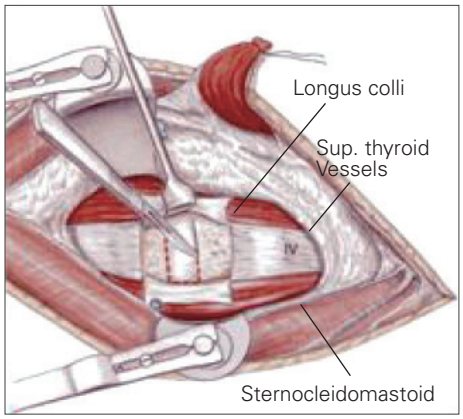


Figure 6

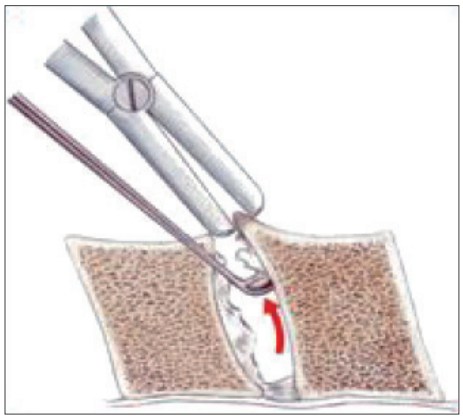


Figure 7

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.

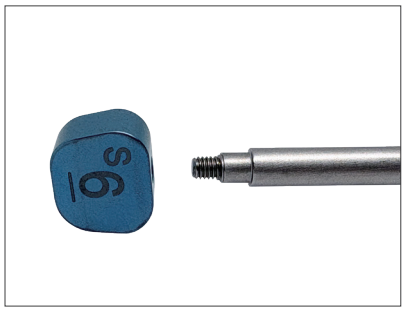


Figure 6

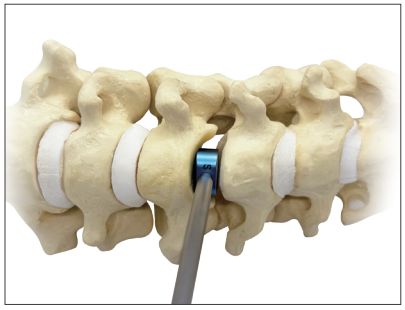


Figure 7

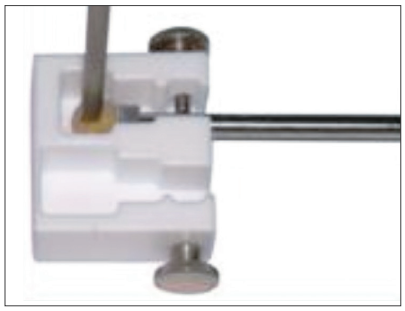


Figure 8

Trialing & Implanting

Step 1

After removing the remaining injured disc, the ***trial (254-0601~254-0612)*** is connected to the ***6mm Trial Driver (218-0806)*** by screwing in.
Based on the preoperative imaging and surgical technique, choose a trial of the appropriate size and carefully insert it into the disc space. Sequentially trial until a desired fit within the disc space is achieved.

The trial should provide optimal height restoration, and good segmental stability. Verify correct sizing with lateral radiographic imaging.

Step 2

Implant Inserter (232-1704) is inserted into the ***Inserter Sleeve (232-1702)***. The Insertor is positioned onto the implant by screwing in.

Step 3

Put the implant onto the ***Bone Graft Block (232-2901)*** and fill it with bone graft by using ***Bone Graft Impactor (218-3301)***.

Step 4

Remove the trial and insert the implant into the disc space. Verify the position of the implant with radiographic imaging before removing the Insertor.

PRECAUTION: Insert the implant with care and avoid using excessive impaction force to prevent damage to the implant or surrounding tissue.

Combo® Cervical Implants Specification

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

254-0601~254-0612
5~10mm Trial

218-0806
6mm Trial Driver

232-1704
Implant Inserter

232-1702
Inserter Sleeve

232-2901
Bone Graft Block

218-3301
Bone Graft Impactor

232-1703
Safety Stop
Inserter Sleeve

General Warnings

The above description is only the standard installing procedure of the Combo® Cervical Disc Cage. Since every patients' 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 actively 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 mean 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.

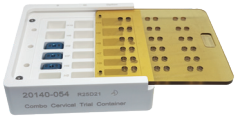
E Warnnings

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 do not have the same resistance as the normal, healthy spine. So we can not forecast the implant could bear the load of the body in no other assistants condition.
3. The Implant may collapse under a heavy load and interrupt the bone heal 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 reuse. A removed implant can not implant into human body again.

Instruments

Cat.No.	Description	
218-0806	6mm Trial Driver	
218-3301	Bone Graft Impactor	
254-0601	L12×W14×H5mm Trial	
254-0602	L12×W14×H6mm Trial	
254-0603	L12×W14×H7mm Trial	
254-0604	L12×W14×H8mm Trial	
254-0605	L12×W14×H9mm Trial	
254-0606	L12×W14×H10mm Trial	
254-0607	L14×W15×H5mm Trial	
254-0608	L14×W15×H6mm Trial	
254-0609	L14×W15×H7mm Trial	
254-0610	L14×W15×H8mm Trial	
254-0611	L14×W15×H9mm Trial	
254-0612	L14×W15×H10mm Trial	
232-1702	Inserter Sleeve	
232-1703	Safety Stop Inserter Sleeve	
232-1704	Implant Inserter	
232-2901	Bone Graft Template	

* Option

Cat.No.	Description	
20140-054	Trial Block	
99901-005	Cervical Cage Case, Metal Lid	
99903-005	Cervical Cage Case, Plasty Lid*	

* Option

STERILIZATION:

The cage had been sterilized by gamma radiation (SAL 10^{-6}) 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 instrumets, please refer to its Catalog.

Note

Note

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