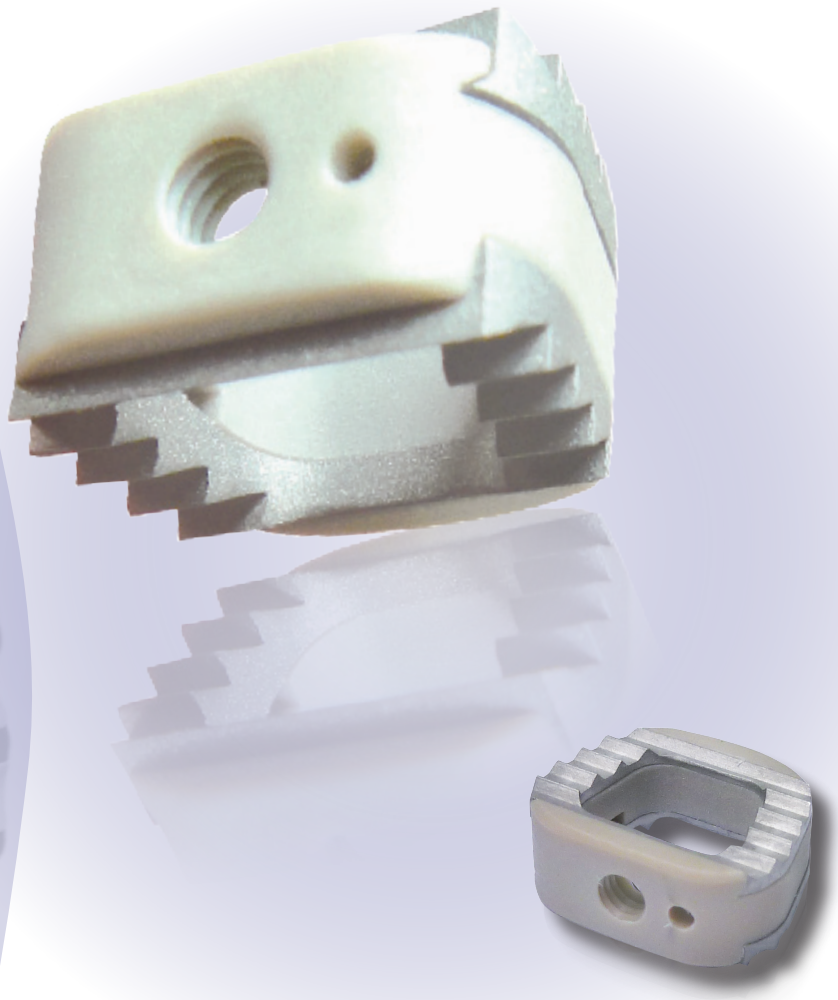
Combo® Cervical Disc Cage



Technique Guide

A-SPINE

Contents

Introduction

The anterior spinal fusion surgical technique 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 surgery has been the implantation of intradiscal spacer with capability of enhancing the success of bone graft fusion. The goals of this device are by the design and material of this device, to eliminate or to reduce patient's symptom and promote long term stability of the implant through the successful Disc at the lesion site to the adjacent vertebrae of the cervical spine.

Design Rationale

1. material：

The Combo® Cervical Disc Cage is made of surgical PEEK, Polyetheretherketone, a high performance composite material lighter and Ti6Al4V alloy, with elastic modulus close to human cancellous bone, making it a better implant material for patients with less occurrence of stress shielding.

2. shape：

Two distinctive parts of upper anterior cervical spine (C2~C4) are the beak shape-like interior edge of cervical vertebrae; the endplate of inferior body has obvious concavity. In order not to jeopardize the vertebrae cortex and to meet the concave curvature of the inferior end plate, the Combo® Disc Cage is designed in trapezoid shape with superior oval build up for promoting spinal stability with increased contact surface area with vertebrae.

Indications

1. Degenerative Disc Disease(DDD) and Degenerative Cervical Scoliosis at 1 or 2 levels from C3 to C7.
2. Grade 1 spondylolisthesis or retrolisthesis at the involved level(s).
3. Anterior approach for cervical.

Contraindications

1. Severe osteoporosis.
2. Active infection of the involved vertebral bodies.

Sterilization

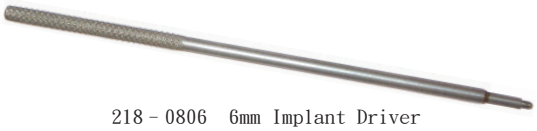
1. Combo® Cervical Disc Cage has been sterilized with gamma radiation (SAL 10-6) (dose 25 KGy).
2. When the sterile package is damaged, please return this product to us for exchange or sterilize thisproduct with medical autoclave at 121°C(250°F) 20 PSIG for 30 minutes. Once sterilization is complete, this device is ready to use following hospital sterilization protocol.

Components

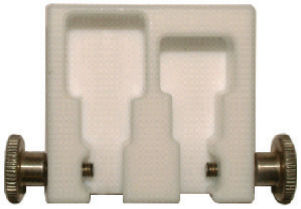
The implant is made of Polyetheretherketone (PEEK) And Ti6Al4V .

Instruments

The appropriate tools to effect proper placement of the Combo® Cervical Disc Cage are assembled in autoclavable kits



218－0806 6mm Implant Driver



232－2901 Bone Graft Template

232－1702 Cervical PEEK Insertor（Straight）

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

218－3301 Bone Graft Impactor

Instruments for sterilization：All instruments should be sterilized by steam autoclave following the instructions of the sterilizer manufacturer according to the type of sterilizer used and the method in accordance with the internal hospital guidelines to achieve the degree of sterility of 10-6. The suggested parameters are as follow:

1. Steam Wrapped Gravity Cycle at 121°C/250°F for 30 minutes.
2. Steam Prevacuum Cycle at 132°C/270°F for 4 minutes.

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

Pre-operation Announcements of Anterior Cervical Surgery

A. 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.

B. 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.

• Caution: Care should be taken to avoid overstretching the brachial plexus.

• One iliac crest or leg is placed, padded and p repared for autologous bone graft harvesting.

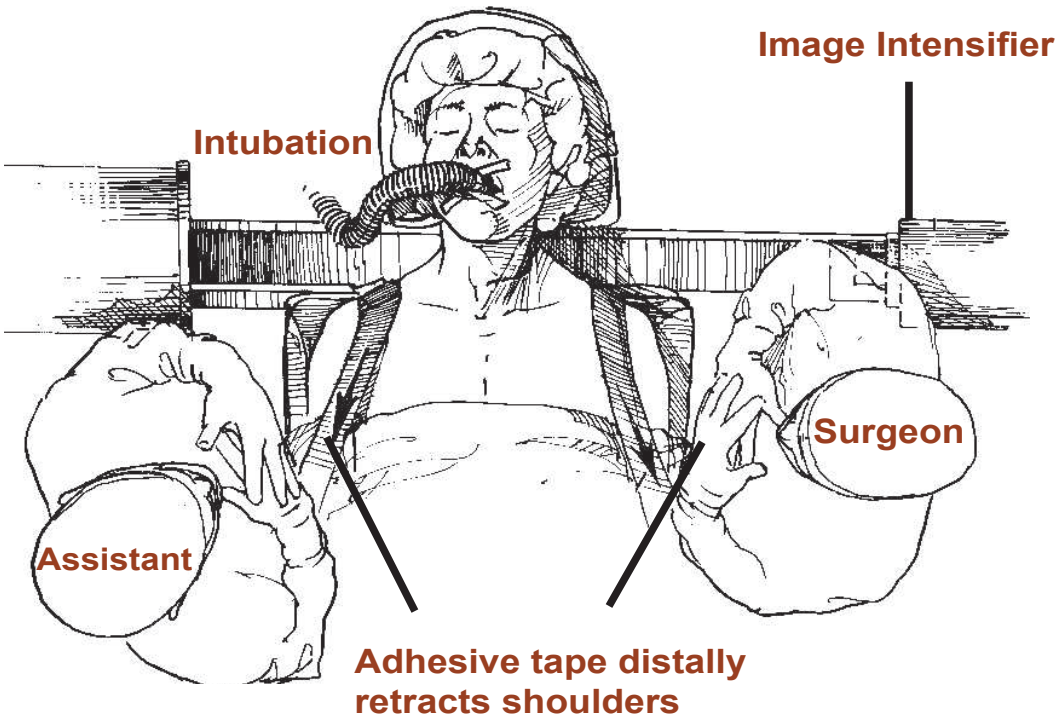


Fig.1

C. Surgical Procedure

A transverse incision parallel to the neck fold is indicated to expose one or two segments, while a longitudinal incision anterior to the sternocleidomastoid muscle is preferred for a broad exposure of several segments of the cervical spine. After incision, the platysma muscle is divided by the direction of its' fiber and retracted to both sides for exposing the superficial cervical fascia. This fascia is divided at the junction of the anterior border of the sternocleidomastoid muscle. If the omohyoid muscle runs transversely across the operative field, can be divided by two ligatures and retracted bilaterally. (Fig. 2 & 3)

Note: Protection of the superior laryngeal nerve should be noted to avoid postoperative hoarseness and speech disorder.

The deep prevertebral fascia is divided from the midline and dissected laterally to the long muscle of the neck, followed by the elevation with rasp on both side on the anterior longitudinal ligament. With a longitudinal resection of ligament, the anterior surface of cervical vertebrae is exposed. (Figure 4)

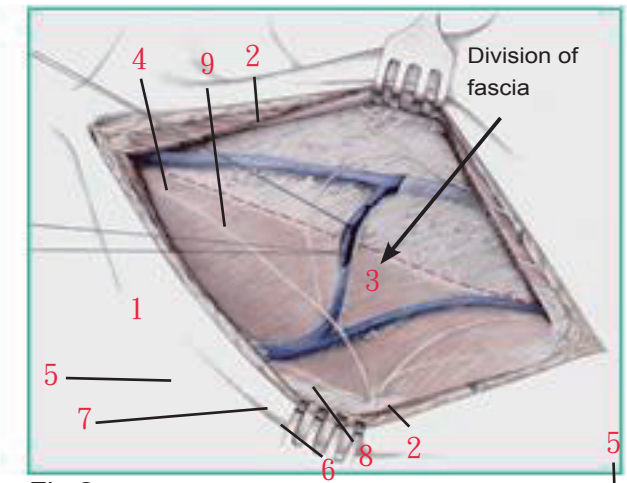


Fig.2

1. Sternocleidomastoid muscle with superficial cervical fascia
2. Platysma muscle, cut
3. Superficial cervical fascia
4. Anterior jugular vein
5. External jugular vein
6. Punctum nervosum
7. Transverse nerve of the neck
8. Great auricular nerve
9. Superficial ansa cervicalis

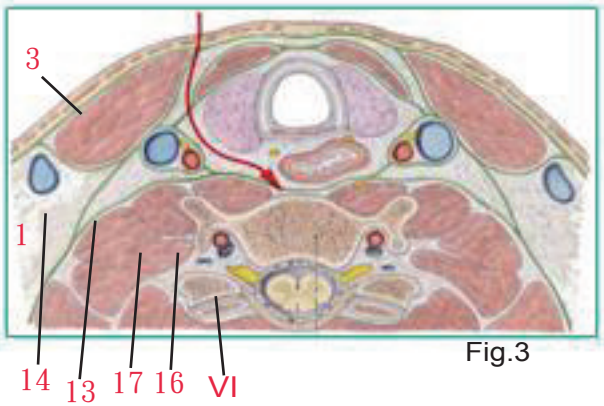


Fig.3

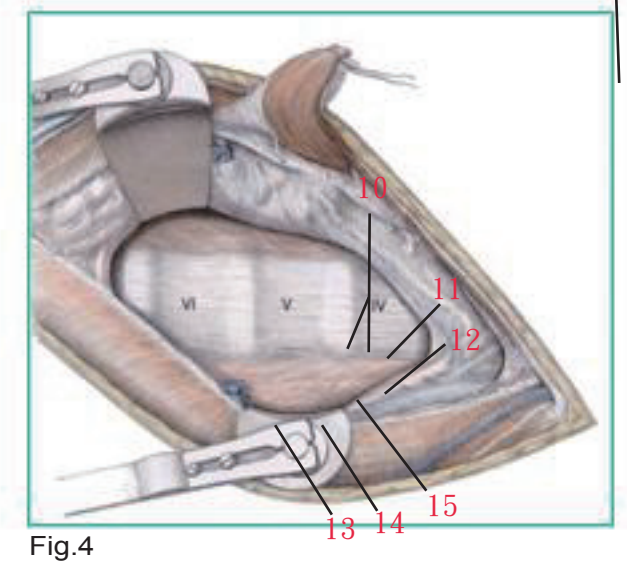


Fig.4

10. Superior thyroid artery & vein
11. Lingual artery
12. External carotid artery
13. Common carotid artery
14. Internal jugular vein
15. Facial vein
16. Prevertebral cervical fascia
17. Long muscle of the neck

IV~VI C4~C6 Cervical vertebrae

Step 2: Discectomy

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

• 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. 5)

• 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.6)

• 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.

• The maximal expansion of the intervertebral space and exact measurement of graft size is conducted with Caspar Distractor. (Fig. 7)

• The Fixation Pins of the Caspar Distractor are inserted into the vertebraes at the midline of the anterior cortex.

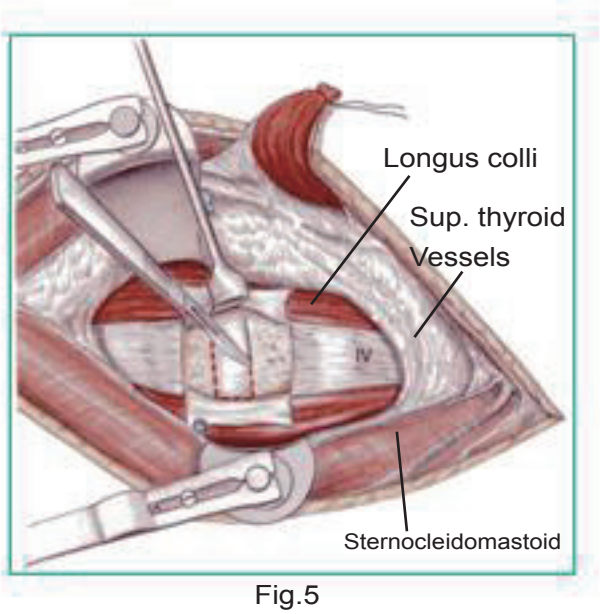


Fig.5

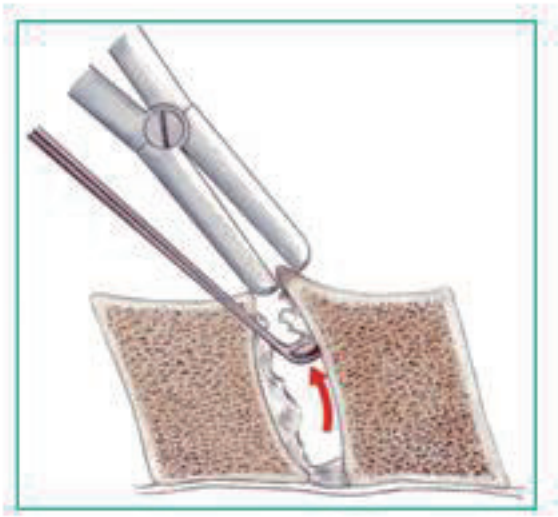


Fig.6

Fig.7

Step 3 : Trialing & Implanting

218-0806
6mm Implant driver

・After remove the remaining injured disc, use the **6 mm Implant Driver** (218-0806) to screw tightening the **Trial** inserting & pushinginto the space properly.

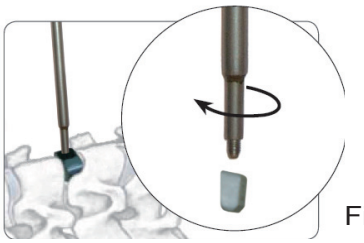


Fig.8

・Released the **Carspar Retractor**, the superior and inferior vertebral bodies contracted automatically, then to feel out the space tension by pulling straight up on the handle of the **Trial** slightly.

・If the trial pulls out easily, retracting the **Carspar Retractor** and removed the former **Trial** and repeat these procedures by using the larger inserting the affected disc gradually.

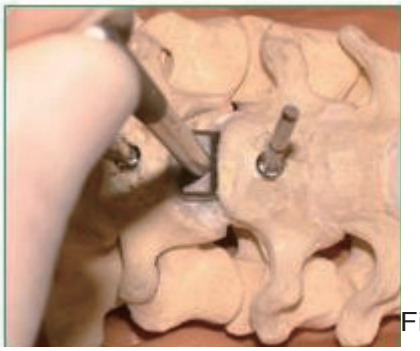


Fig.9

Note :

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

2 . The 5mm ~ 10mm Trial (5^0) (232-0665~232-0670) is for the Combo (165-25128H~165-30128H) implant.

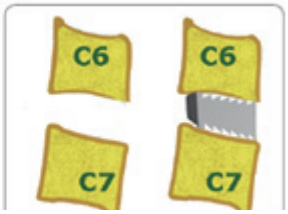


Fig.10

・ Take a same sized implant onto the top of the Cervical PEEK Insertor (Straight) (232-1702) and screwed tightenedly.

・Put the cage into the bone graft template and fill it with the autogenous bone or other bone substitute.

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

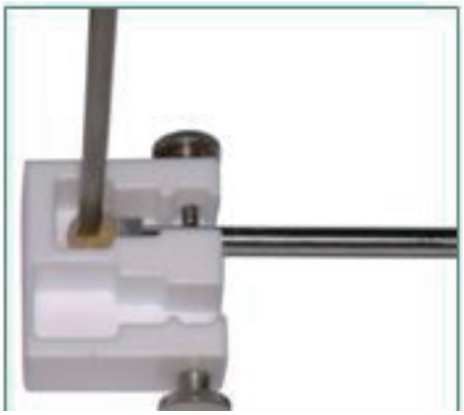


Fig.11

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 limitations 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 helpgenerally 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. 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. Sensitivity to the Poly-ether-ether-ketone meterial or allergic reaction to a foreign body.
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.

F. Possible Risks and Complications

1. Implant improperly positioned.
2. Failure to mobilize diaphragm adequately at TL junction.
3. Failure to fashion graft to properly fit the resection gap.
4. Failure to properly fill and compress bone graft material into the bony defect.
5. Failure to carefully dissect and retract the psoas muscle away from the spinal segments to
   avoid nerve root damage.

G. Warnnings

1. It is important to choose the correct implant. The correct size, shape and structure of the implant could increasing the efficiency of the fusion and patient satisfactory. The size, shape and structure stress of the implant is restricted by the human body, proper

choose could minimize the danger of the surgery. In addition, 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 wouldshare 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.

冠亞生技股份有限公司

A-SPINE ASIA CO., LTD

11F, NO.1,Alley 30,Lane 358 Ruiguang Rd., Neihu District, Taipei, 114 Taiwan

Tel: 886-2-2627-2977 Fax: 886-2-6606-5955
E-mail: service@aspine.com.tw
www.aspine.com.tw

European Representative :
A-SPINE Deutschland GmbH Prager Str.34-04317 Leipzig, Germany

GMP
CE 0434

T-PKVDS-001-BT 04/12