A-SPINE

# Polymer Disc Spacer
## Combo Lumbar Disc Cage

English 繁體中文

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## Polymer Disc Spacer
### Combo Lumbar Disc Cage

**DESCRIPTION**

The Combo Lumbar Disc Cage is made of PEEK (ASTM F2026), Tantalum (ASTM F560/ ISO 13782) and Titanium alloy (Ti6Al4V, ASTM F136/ISO 5832-3). The instruments are designed for implantations of the Combo Lumbar Disc Cage. The method of implanting is described in the Combo Lumbar Disc Cage Surgical Technical Manual.

**INDICATIONS**

The diseases use with autogenous bone graft for spinal interbody fusion operation, including:

- 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
- Grade 1 spondylolisthesis or retrolisthesis at the involved level (s)
- Revision surgery for failed column operation or post-operation instability
- Stenosis
- Pseudarthrodesis at the lumbar
- Posterior or anterior approach for lumbar

**CONTRAINDICATIONS**

- Patients with fever or leukocytosis
- Patients with infections associated with the spine (e.g. spondylodiscitis)
- Patients with a history of material allergy or who tend to react to foreign bodies
- 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
- Patients with inadequate bone quality or quantity (e.g. severe osteoporosis, osteopenia, osteomyelitis)
- Pregnancy



**PRECAUTIONS**

- The surgeon must be thoroughly knowledgeable for the mechanical properties and limitations of the Combo Lumbar Disc Cage. Adequate training, careful reading of the technical manual and experience in the surgical technique is advised before using the Combo Lumbar Disc Cage.
- Patients should be informed of the following reason to cause the possible adverse effects: Obesity, coronary heart disease, pregnant woman, above Grade 2 Spondylolisthesis without reduction operation, whole body or nerve-end disease, serious osteoporosis, cartilage, steroids treatment necessarily or abuse medicament.
- It is better to implant internal fixator for increasing the stability of spine.
- It is not allowed to be re-used after the implant contacts physical tissue or body fluid. The reused product will be caused the serious cross-infection.

**POSSIBLE ADVERSE EFFECTS**

The following things 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 they are important considerations particular to metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

- Dural leak
- Nerve damage due to surgical trauma
- Infection
- Pain, discomfort or abnormal sensations due to presence of the device
- Sensitivity or allergic reaction to a foreign body
- Bending or fracture of the implant; loosening of the implant
- Delayed union or nonunion
- Decrease in bone density due to stress shielding
- Bursitis

**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 provided Non-Sterile to hospital. A-SPINE suggests the device should be sterilized via steam sterilization (under 121 ℃/ 250 ℉, 20 PSIG for 30 mins) to assure SAL ($10^{-6}$).

**SERVICING**
Please contact customer service center (+886-2-2926-7088), the authorized distributor or dealer, meanwhile, please offer patients' information and item needed in order to preparation and delivery.

Manufacturer

**A-SPINE Asia Co., Ltd.**
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繁體中文

# 康鉑腰椎椎間盤融合器
## Combo Lumbar Disc Cage

衛署醫器製字第003878號

**使用前請務必詳閱原廠之使用說明書並遵照指示使用。**

**產品說明：**
康鉑腰椎椎間盤融合器為椎體間植入物，由聚醚醚酮(PEEK)製成，並使用符合ISO 5832-3之鈦合金(Ti6Al4V)材料為X-ray顯影之用，並取尾碼2H為噴砂處理及8H為陽極處理做區分。
所使用之器械均針對植入物而特別設計，技術手冊內亦有說明。

**適應症：**
- 第二腰椎至第一薦椎(L2~S1)椎間盤退變之脊椎後路手術，如椎間盤摘除減壓、神經孔擴大成型等。
- 脊柱二次手術或脊柱不穩定施行椎間盤固定手術。
- 腰椎間隙狹窄或假性關節病變。
- 脊柱椎體滑脫、峽部骨折、或退化造成不穩定，經使用椎弓根釘固定後之椎間盤填充用。

**禁忌症：**
- 嚴重的骨質疏鬆症。
- 創傷或病灶之椎體有活動期之感染。

**注意事項：**
- 骨科與神經外科醫師應對此植入物及技術手冊有充份之研究與訓練，方能確實瞭解對此植入物的限制因素及對病患之影響。
- 建議以脊椎內固定器加以固定，穩定性更佳。
- 可在兩個融合器之間隙植骨，作椎體融合術或後側方植骨融合術，醫師亦可依病情狀況當 interbody fusion 使用。
- 可能影響安全及療效者包括：
  過度肥胖、冠心症、孕婦、未經復位手術之第二級以上之椎體滑脫、全身或末梢疾病、嚴重的骨質疏鬆症或軟骨症、需使用類



  固醇治療或藥物濫用者。
- 除非病患生理解剖或手術部位暴露不足等因素外，應儘可能在每一椎節放置兩個「椎間盤融合器」。
- 本植入物之產品為已經過γ-Ray照射滅菌，手術全程應謹慎以避免污染，如發現包裝破損可向本公司提出更換。
- 本植入物接觸人體組織或體液後絕不可回收重複使用。
- 器械使用前需經高溫高壓(250° F/121°C, 20 PSI, 30min)滅菌後方可使用。

**可能的不良影響：**
手術醫師應在術前將可能發生之不良影響告知病患：
- 硬脊膜破裂
- 因手術創傷造成神經受損
- 感染
- 延遲癒合或不癒合
- 對植入物之材質過敏
- 植入物之抗力作使骨密度降低

**售後服務：**
如有移除植入物之需要，請連絡本公司客戶服務中心（02 –2926-7088），同時請提供病患資料及使用品項，以便備妥所需器械與出貨。

醫療器材商名稱：冠亞生技股份有限公司
醫療器材商地址：新北市永和區成功路一段80號20樓
製造業者名稱：冠亞生技股份有限公司新店廠
製造業者地址：新北市新店區復興里復興路43號 (1樓)