A-SPINE

Polymer Disc Spacer
Combo Cervical Disc Cage

English 繁體中文

I-PDS-004-HE I-PDS-020-DT

October 2022

C0101-Z-z05 V5

EN

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Combo Cervical Disc Cage

DESCRIPTION

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

INDICATIONS

Indications for fusion procedures are for example:

- Degenerative disk disease
- Spondylolisthesis and retrolisthesis grade 1
- Degenerative scoliosis
- Revision operation
- Pseudarthrosis

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 Cervical Disc Cage. Adequate training, careful reading of the technical manual and experience in the surgical technique is advised before using the Combo Cervical 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

A-SPINE Asia Co., Ltd.
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繁體中文

康鉑頸椎椎間盤融合器
Combo Cervical Disc Cage

衛署醫器製字第004070號

使用前請務必詳閱原廠之使用說明書並遵照指示使用。

說明：
康鉑頸椎椎間盤融合器為脊椎手術的植入裝置，用於作為頸椎椎間的填充塊，有支撐與穩定脊椎之功效，康鉑頸椎椎間盤融合器為圓方體中央有上下方向的孔洞，可填入骨頭或骨替代物，促進脊椎融合。植入物有不同的尺寸大小，可依據患者的需求而選用。融合器材質為符合ASTM F2026之聚醚醚酮(PEEK)製成，並使用符合ASTM F136之鈦合金(Ti6Al4V ELI)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。

適應症：

頸椎(C2~C7)椎間盤退變之脊椎前路手術(由脊椎前方植入之手術方法)。
頸椎脊柱脫位、滑脫與不穩定之治療與二次手術之重建。

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：
- 本產品建議須與頸椎固定器一併使用，穩定性更佳。
- 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。
- 可能影響安全及療效則包括：
  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。

- 在每一椎節內僅可放置一顆「椎間融合器」。
- 本植入物之產品為已經過γ-ray照射消毒滅菌，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)消毒滅菌後方可使用。

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
- 對植入物之材質過敏
- 延遲癒合或不癒合
- 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)