ASTA Cervical Interbody Fusion Cage

English 繁體中文

I-PSD-035-AE I-PDS-035-AT

February 2024

C0101-Z-z48 V1

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ASTA Cervical Interbody Fusion Cage

IMPORTANT NOTICE
The users of the ASTA Cervical Interbody Fusion Cage acknowledge that they have read and agreed to the statement in this instruction, ensure that they are familiar with appropriate surgical technique.

INTENDED USE
The ASTA Cervical Interbody Fusion Cage is intended for stabilization and promoting bone fusion during the normal healing process following surgical correction of disorders of the cervical spine. The product should be implanted only by a physician thoroughly knowledgeable in the implant, indications, instruments, and surgical techniques.

DESCRIPTION
The ASTA Cervical Interbody Fusion Cage is used in single- or multi-level cervical spine from C2 to T1 segment. The implant is placed between two vertebral bodies through an anterior approach of the cervical spine to provide stabilization and reduction. Specific instruments have been designed to use with the implant.

MATERIAL
Implant materials listed on packaging include:

- Polyetheretherketone (PEEK) (ASTM F2026)
- Pure titanium coating (ISO 13179-1/ASTM F1580)
- Tantalum markers (ASTM F560)

INDICATION

- Degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by patient history and radiographic studies)
- Spondylolisthesis and retrolisthesis
- Spinal stenosis
- Revision operation
- Pseudarthrosis

CONTRAINDICATIONS
Any medical or surgical condition that may prevent successful implantation, including:

- Patients with acute or chronic infection, fever, or leukocytosis
- Patients with local inflammation
- Morbid obesity
- Pregnancy
- 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 with severe defects in the vertebral structure (partial fractures, congenital deformities)
- Patients with inadequate bone quality or quantity (e.g., severe osteoporosis, osteopenia, osteomyelitis)
- Patients who are in a generally unfavorable medical or psychological state and who could be made worse by the procedure
- Patients with spinal fracture
- Patients with spinal tumor
- Patients with drug or alcohol abuse

POSSIBLE SIDE EFFECTS AND INTERACTIONS
In addition to general surgical risks, potential complications associated with surgery of the disc include, but are not limited to:

- Implant malposition, breakage, loosening, displacement/dislocation
- Spondylolisthesis, pseudoarthrosis, and insufficient fusion
- Breakage of any or all components or instruments
- Foreign body reaction to the implant, including possible development of autoimmune disease, tumors, and/or scarring
- Loss of intervertebral disc height due to removal of healthy bone material
- Stress shielding or fracture at, above or below the surgical site
- Implant placing pressure on surrounding tissues or organs may cause damage to the esophagus or trachea
- Loss of proper spinal curvature, correction, height, and/or reduction
- Changes in bone density and degenerative changes in the region of the adjacent vertebral bodies
- Infections, allergies and/or discitis, arachnoiditis and other forms of inflammatory reactions
- Bleeding and/or hematoma

- Neurological complications caused by over distraction or trauma of the nerve roots or dura
- Deep vein thrombosis, thrombophlebitis, and pulmonary embolism
- Persistent pain and inability to resume daily activities
- Death

GENERAL INFORMATION
The operating surgeon shall devise an operation plan that specifies and accurately documents the following: the selection of implant and sizes, the positioning of implant in the bone, and the location of markings during the operation. The following conditions must be fulfilled prior to surgery:

- All required implants are ready to hand.
- All required instruments for implantation must be available and in working order, including A-SPINE implantation systems.
- Follow all instructions listed in the surgical technique of the implant.
- The operating surgeon and operating room team are thoroughly conversant with the operating technique and with the available range of implants and instruments. Information materials on these subjects must be complete and ready to hand.
- Aseptic operating conditions.
- The operating surgeon is fully conversant with the rules governing medical practice, the current state of scientific knowledge, and the contents of relevant scientific articles by medical authors.

The patient has been informed of the procedure, taking into account the information provided in the sections on indications, contraindications, side effects and interactions, and has documented his/her understanding and consented regarding the following:

- In the case of delayed or incomplete fusion, the implant may break and loosen due to high loads.
- The lifespan of the implant depends mainly on the patient's weight.
- The implant must not be overloaded by extreme strains, hard physical work, or sports.
- Corrective surgery may be necessitated by implant loosening, breakage, or loss of correction.
- Excessive drinking and smoking may increase the risk of insufficient bone fusion and/or failure.
- The patient must undergo regular medical follow-up examinations of the implant.

WARNING AND PRECAUTIONS

- The implant provides support for the normal healing process. It should neither replace normal structures of the body nor permanently bear the loads occurring in the case of incomplete healing.
- Patients should be fully informed of the important medical information in this instruction before surgery.
- It is the responsibility of the operating surgeon to make sure that the surgical procedure is performed appropriately.
- General risk factors associated with surgical procedures that are not described in this instruction.
- The operating surgeon must have a thorough command of both the hands-on and conceptual aspects of the established operating techniques.
- The operating surgeon must be fully conversant with bone anatomy, including the pathways of nerves, blood vessels, muscles, and ligaments.
- A-SPINE is not responsible for any complications arising from incorrect diagnosis, choice of incorrect implant, incorrectly combined implant and/or operating techniques, the limitations of treatment methods, or lack of asepsis.
- The instruction of individual implant must be followed. The surgeon must be fully conversant with the various components before use. He/she should also assemble the implant and make sure that all components and necessary instruments are ready to hand.
- The implant has been tested and approved in combination with A-SPINE instruments. If other combinations are used, the responsibility for such action lies with the operating surgeon.
- Do not, under any circumstances, combine implants from different manufacturers.
- Do not, under any circumstances, use damaged or surgically excised implants.
- Implants that have been used before must not be reused under any circumstances.
- The attending physician shall make decision with regard to the removal of implant that have been used.

CLEANING & STERILIZATION
Prior to use, check the expiration date of the product and verify the integrity of the sterile packaging. The implant comes individually packed in protective packaging that is labeled according to its contents. All packages should be intact upon receiving the product. If the sealed sterilization package is damaged, do not re-sterilize and use the product. Return the product to the manufacturer immediately. The implant is sterilized by gamma radiation.

MRI INFORMATION
The product has not been evaluated for safety, heating, displacement, or compatibility in the magnetic resonance environment.

Manufacturer

A-SPINE

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繁體中文

艾絲達頸椎椎間融合器

ASTA Cervical Interbody Fusion Cage

衛部醫器製字第008107號

注意：請務必詳閱原廠之使用說明書並且遵照指示操作使用

用途目的

本產品用途為頸椎疾病矯正手術後用於穩定以及在正常癒合過程中促進骨融合。本產品只可由對產品、適應症、器械及手術技術相關知識有充分了解的專業醫師進行植入置放。

產品敘述

本產品適用於單節或多節段之頸椎C2-T1節段，透過頸椎前開手術的方式，在椎體間融合術時置入於兩個椎體間，提供穩定及復位。本產品所使用之器械皆針對植入物而特別設計。

材質

列於包裝上的植入物材料：

- 符合 ASTM F2026之聚醚醚酮PEEK
- 符合 ISO 13179-1/ASTM F1580之表面純鈦塗層
- 符合 ASTM F560之鉭線Ta

適應症

- 退化性椎間盤疾病（定義為椎間盤源性疼痛，經病史和放射線攝影檢查確認為椎間盤退化）
- 脊椎滑脫及/或脫位
- 椎管狹窄症
- 二次手術之重建
- 假性關節

禁忌症

任何可能阻礙植入成功的醫療或手術狀況。包括：

- 急性或慢性感染、發燒或白血球異常增多
- 局部發炎
- 病態性肥胖
- 懷孕
- 患有與脊椎相關的感染（例如脊椎椎盤炎）的患者
- 對本材質過敏及/或異物反應
- 嚴重缺陷的脊椎骨性結構(局部骨折、先天性畸形)
- 骨質密度的明顯流失(骨質疏鬆及/或骨質缺乏症)
- 醫療或心理狀況不利於手術或可能因手術而惡化的患者
- 脊椎骨折
- 脊椎腫瘤
- 藥物濫用或酗酒

副作用與交互作用

除手術相關風險外，與椎間盤手術有關潛在的併發症包括但不限於：

- 植入物位置不正、斷裂、鬆動、位移/錯位
- 植入物滑脫、假關節形成、融合不足
- 任何或所有組件或器械破損
- 對植入物產生異物反應，包括可能形成自體免疫疾病、腫瘤及/或疤痕
- 由於健康骨質移除所造成的椎間盤高度損失
- 在手術部位、其上方或下方發生應力遮蔽或骨折
- 周圍組織或器官壓力，可能導致食道或氣管被組件造成傷害
- 喪失適當的脊椎彎曲度、矯正度、身高及/或復位程度
- 骨質密度改變、相鄰椎體區域內的退化性變化
- 感染、過敏及/或椎間盤炎、蛛網膜炎及其他形式的發炎反應
- 出血及/或血腫
- 神經系統的併發症造成神經根或硬膜的過度牽引或創傷

- 深層靜脈血栓、血栓靜脈炎、肺栓塞
- 持續性疼痛、無法恢復日常活動
- 死亡

一般資訊

手術醫師應擬定手術計畫並可具體說明與記錄相關事項，包含植入物組件及規格尺寸的選擇、在骨頭中植入物組件的定位以及手術過程中標記的位置。

手術執行前必須先滿足下述條件：

- 已備妥所有需要的植入物組件
- 必須可依作業順序取得所有需要的植入器械，包括：原廠植入系統
- 務必遵守各項列於本產品相關手術技術手冊之說明
- 手術醫師與手術室團隊必須非常熟悉手術技術及植入物與器械的可用範圍；關於這些題材的資訊材料必須非常完整且完備
- 無菌手術條件
- 手術醫師完全了解有關醫療實務、當前科學知識狀態與身為醫學作者的相關科學文章內容規定

已告知患者有關本說明書內提及的適應症、禁忌症、副作用與交互作用等手術資訊與程序，並要求他/她簽署

已了解有關下述重點的同意書：

- 萬一發生融合延遲或不完整的情況，植入物會因為高承載而破裂與鬆脫
- 植入物的使用壽命主要取決於患者體重
- 不可因極度張力、重度身體勞動或運動造成植入物構成要件的過載
- 植入物鬆脫、斷裂或矯正失敗時必須接受矯正手術
- 過量飲酒及抽菸者會增加骨頭融合不足及/或失敗之風險
- 患者必須定期接受植入物組件的醫療追蹤檢查

安全注意事項

- 本產品可提供正常癒合過程之支撐，不可用於取代正常身體結構，亦不可作為未癒合處的永久負重支撐
- 應於手術前詳實告知病患本說明書所含重要醫療資訊
- 由手術醫師負責確認手術程序是否適當執行
- 未於此說明書中說明與手術相關的一般風險因素

- 手術醫師必須能完全掌控已確立手術技術的實作與概念層面
- 手術醫師須完全熟悉骨頭解剖結構，包括神經、血管、肌肉與韌帶路徑
- 對於任何由錯誤診斷、選擇錯誤的植入物、錯誤地結合植入物組件和/或操作技術、治療方法的限制或無菌處理缺失所引起的併發症，原廠皆不承擔任何負責
- 必須遵照個別原廠植入物組件的使用說明，手術醫師在使用前應孰悉各種組件，亦應親自組裝本裝置，並確認所有零件與必要器械皆已備妥
- 植入物的組件已經過測試及核准與原廠組件結合，若使用其他與原廠不同來源的裝置組合，則應由手術醫師對此行為負責
- 任何情況下，請勿組合來自不同製造業者的植入物組件
- 任何情況下，請勿使用已損壞或經手術切除的組件
- 任何情況下，已使用過的植入物不可重複使用
- 應由主治醫師決定是否移除已使用的植入物組件

包裝及滅菌

使用前，請先檢查產品保存期限並確認無菌包裝的完整性。植入物組件為單獨包裝並包裝在貼有標籤的保護性包裝中，收到產品時所有組件包裝應完整無缺，一旦密封的滅菌包裝破損，不可自行對產品進行重複滅菌及使用，應立即退回原廠。植入物組件經過 gamma 射線滅菌。

核磁共振造影(MRI)資訊

本產品尚未在核磁共振環境下評估其安全性、加熱、位移或相容性。

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