SmartLoc Omega Spinal Fixation System Instructions for Use

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SmartLoc Omega Spinal Fixation System Instructions for Use

IMPORTANT NOTICE

The users of the SmartLoc Omega Spinal Fixation System acknowledge that they have read and agreed to the statement in this insert, which is considered contractual.

DESCRIPTION

The SmartLoc Omega Spinal Fixation System is a spinal fixation system composed of pedicle screws, smooth rods, transverse link assemblies, connectors for spinal surgery. Various sizes and styles of the implants are available for optimal adaptation of the pathology of the individual patient. Specific instruments have been designed for use with these implants. For the purpose, function and method of these instruments, please refer to the detail instruction of the SmartLoc Omega Spinal Fixation System Surgical Technique.

MATERIAL

The SmartLoc Omega Spinal Fixation System has different rod materials. These materials include Titanium alloy (Ti6Al4V, ASTM F136/ISO 5832-3), Cobalt-Chromium alloy (ASTM F1537/ISO 5832-12), and PEEK (ASTM F2026) with Tantalum (ASTM F560/ISO 13782). All components aside from the rods are made of Titanium alloy (Ti6Al4V, ASTM F136/ISO 5832-3).

INTENDED USE

The SmartLoc Omega Spinal Fixation System is a pedicle screw fixation intended to use (in the thoracic, lumbar, and sacral spine segments) in skeletally mature patients as an adjunct to fusion for immobilization and stabilization, who present acute or chronic instabilities or deformities.

INDICATIONS

- Degenerative disc disease
- Spondylolisthesis
- Trauma (i.e., fracture or dislocation)
- Spinal stenosis
- Deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis)
- Tumor
- Pseudoarthrosis
- Failed previous fusion

In osteoporotic patients, the utilization of cannulated screws, cannulated long-arm screws, perforated screws and/or perforated long-arm screws, in combination with bone cement fixation, is appropriate for the described indications.

CONTRAINDICATIONS

- Any active or suspected latent infection of the spine
- Bone stock abnormalities, or deficiency which can not provide adequate support and/or fixation to the implants
- Pathological obesity
- Open wounds
- Severe osteophyte
- Pregnancy
- Patients with a history of material allergy or who tend to react to foreign bodies
- In osteoporotic patients, screws were utilized without the application of cement.

WARNING AND PRECAUTIONS

- The implants must be implanted only by surgeons having undergone the necessary training in spine surgery the implantation of which must be in accordance with the medical and surgical indications, the potential risks and limitations related to this type of surgery, the contraindications, precautions, and complications.
- Prior to clinical use of these implants, the operating surgeons should thoroughly understand all aspects of the surgical procedure and limitations of the spinal fixation system. The SmartLoc Omega Spinal Fixation System is limited for use by surgeons familiar with the pre- and post-operative treatment, surgical technique, cautions and potential risks related with such spinal surgery. The sufficiency of knowledge of surgical technique, adequate reduction, selection and placement of implants, pre and post-operative patient management are considered essential factors to the delivery of a successful surgical treatment.
- Appropriate size selection, material, shape, placement, and fixation play critical role in implant service life that the decision of selecting proper implant is very important. Implant being properly selected minimize potential risk of implant failure to the least, thus, close approximation of the size, shape, material, strength of implants to the skeleton of the individual patient renders maximum result to the implant service life.
- The metallic implant does not bear equal strength to resist stress as healthy human bone does. Until maturation of the grafted fusion mass confirmed, implant must not be subject to full weight bearing without additional supports, or implant failure may occur.
- The implant service life may be shortened in case of delay union or nonunion due to metal fatigue. Any scratch, or wear during surgical implantation may become the factor that lead to acceleration of metal fatigue.
- Great care must be taken to protect the implants from mars, nicks and notches generated by the contact with other metal or abrasive objects. Such injuries produce defects in surface finish of the implants as well as internal stresses which in terms, may become the focal point of implant failure.
- Contact of dissimilar metals may accelerate metal corrosion process that occurs on all implanted metals and alloys. The occurrence of corrosion may accelerate fatigue fracture of implants and the increase of metal compound release into human body. Thus, the material of internal fixation such as screws, hooks, connectors, and rods, which may come into contact with another metallic object, should be made of same or compatible

metals. It is suggested that the SmartLoc Omega Spinal Fixation System not to be used with another system from different sources, manufacturers, or material. If such mixing occurs, A-SPINE claims no responsibility.
- Implant must not be reused. Discard all implants immediately after removal of implants from human body, or mishandled intra-operatively. The reused product will be caused the serious cross-infection.
- X-ray guidance or other image guiding system is recommended to facilitate precise positioning, and reduction in order to avoid or minimize the risk of complications.
- The SmartLoc Omega Spinal Fixation System consists of implants such as screws, rods, as well as a dedicated set of instruments. Unless otherwise indicated, other instruments should not be used with this system for they may not be compatible the result of which will not be guaranteed.
- Smoking patients have been shown to exhibit an increased incidence of non-union. Such patients should be warmed of this fact as well as its potential consequence.
- In case that the involvement of patient's occupation or activity which applies excessive load to the implant, failure of implant may occur
- In some rare cases, progression of degenerative disease may be so advanced that the expected service life of such device may be substantially decreased. In such case, orthopaedic devices may be considered only as a delaying technique or to provide temporary relief.
- Patients receiving implant should be instructed in full detail of the limitations of the implants, including but not limited to the impact of excessive loading through patients' weight or activity, and should be taught to govern their activities accordingly. Patients should clearly understand that the implanted device is not as strong as normal health bone and will bend, deform, loose, or break when excessive loads are applied on. A patient who is active, debilitated or demented and cannot use weight supporting device properly may be at risk particularly during postoperative rehabilitation period.
- Removing an unloosened spinal screw may require the use of special instrument to disrupt the interface between implant surface and bone tissue. Prior surgery practice of the use of this technique may be required.
- Prior to making decision of implant removal, surgeon should take into consideration the risk of additional surgery to the patient and the difficulty of removal.

WARNING

The safety and effectiveness of pedicle screw fixation system have been confirmed only under the conditions of deformity or significant instability of the spine requiring fusion with instrumentation. These conditions are: significant instability or deformity of the thoracic, lumbar and sacral spine caused by degenerative spondylolisthesis with distinctive evidence of neurological impairment, scoliosis, fracture, dislocation, spinal tumor, kyphotic deformity, and failed previous fusion. The safety and effectiveness of these devices for other condition remain unknown.

POSSIBLE SIDE EFFECTS

Patients should be advised prior to implantation surgery the possible side effects of such surgeries including:

- Bleeding or hematoma.
- Infection.
- Neurological complications, paralysis, soft tissue lesion, breakage, deformation, or migration of the implants.
- Pain or/and abnormal sensation due to implants.
- Bending, deformation, migration, fracture, or loosening of implants.
- Foreign body allergic reaction to implants.
- Presence of metallic micro particle around the implants.
- Non-union, delayed union, mal-union.
- Bursitis, skin ulcers and or other complications.
- Failure to thoroughly remove the intervertebral disc or properly reposition the sternocleidomastoid muscle can lead to nerve root compression or injury.

Possible side effects including but not limited to the above, may necessitate further surgical treatment.

CLEANING & STERILIZATION

- All implants (except PEEK Rods) and instruments should be cleaned by ultrasounic cleaner with stilled water for 5 minutes.
  CAUTION: The use of sodium hydroxide (NaOH) is prohibited.
- Avoid the use of corrosive products and/or instruments including abrasive sponges and metal brushes.
- Verify that all instruments are in operative condition prior to sterilization.
- Instruction for sterilization: The implants and 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:
  - Steam Wrapped Gravity Cycle at 121 ℃/ 250 ℉ for 30 minutes, dry time for 30 minutes.
  - Steam Wrapped Dynamic-Air-Removal (Pre-vacuum) Cycle at 132 ℃/ 270 ℉ for 4 minutes, dry time for 30 minutes.

After processing, please inspect the cleaning, damage and function of implants and instruments prior to use.

PACKAGE, LABELING & STORAGE

- The PEEK Rods had been sterilized by gamma radiation. It should avoid contaminating while operation process. It is necessary to exchange if the packaging has been broken without reason.
- The other implants and instruments are supplied NON-STERILE.
- The implants are delivered in individual packages. The implant, package, and insert must be intact at the time of receipt. All legal information required for this type of implant is given in the labeling and the insert of each package.
- The implants may be supplied as a complete set in specially designed trays or boxes, which can be sterilized directly.

- Use care in handling and storage of implants. Cutting, aggressive bending, or scratching of implant surface can significantly reduce the strength & fatigue resistance of the implants. This may cause cracks or non-visible internal stresses that lead to fracture of the implants.
- Implants and instruments should be stored away from the corrosive environments such as salt air, moisture.
- Routine inspection and trial assembly of the instruments and implants are recommended to verify if damage occurred in storage or prior surgery.

SERVICE

When the following conditions occur, please contact A-SPINE, the authorized distributor or dealer. The information should include product description, reference number, lot number, your full contact information, and the type of incident, an accurate description of the incident and consequences, and other related technical information to assist future investigation. Please indicate if a written report is required from A-SPINE, the authorized distributor or dealer.

- In case of claim of dissatisfaction of the identification, reliability, safety, efficacy, performance, or any defect of the SmartLoc Omega Spinal Fixation System
- Upon receipt of implant, implant defect or damage to the package or insert
- Any serious side effect on patient health or safety, or any life threatening issue or death

Manufacturer

A-SPINE

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繁體中文

史麥特歐美加脊椎固定系統

SmartLoc Omega Spinal Fixation System

衛署醫器製字第002908號

使用前請務必詳閱原廠之使用說明書並遵照指示使用。

產品敘述：
史麥特歐美加脊椎固定系統為一套用於脊椎手術之脊椎固定系統，由椎弓根螺釘、平滑桿、橫向連結器、延伸聯結器等組件構成， 本系統組件樣式尺寸一應俱全，俾符合不同患者之需求， 所使用之器械均針對植入物而特別設計，其目的、功能、方法請參閱技術手冊之說明。

材質：
史麥特歐美加脊椎固定系統-不同系統滑桿分別使用符合:
ISO 5832-3或ASTM F136規範之鈦合金Ti6Al4V、ISO 5832-12或ASTM F1537規範之鈷鉻鉬合金、ASTM F2026規範之PEEK製成。
除前述滑桿，史麥特歐美加脊椎固定系統內所有組件均符合ISO 5832-3或ASTM F136規範之鈦合金Ti6Al4V製成。

適應症：
史麥特歐美加脊椎固定系統係椎弓根骨螺釘固定系統，為骨骼發展成熟、且患有下列急性或慢性症狀之患者提供固定及穩定之效果，患者脊椎並接受自體骨移植術及植入物，俟骨組織融合時取出植入物。

- 適用於胸椎、腰椎及薦椎(T1~S1)。
- 椎體骨折與腫瘤切除後之固定。
- 脊柱側彎與前彎。
- 脊椎滑脫（第Ⅰ,Ⅱ,Ⅲ級）。

- 椎間盤病變。
- 脊椎不穩定。

骨質疏鬆症患者使用中空螺釘、中空長螺釘、側孔螺釘、側孔長螺釘併用骨水泥固定時，可適用於上述適應症。

禁忌症：
- 創傷或病灶之椎體有活動期感染。
- 骨頭發育不完全或骨質異常不能確保螺釘之固定。
- 病態性肥胖。
- 開放性創傷。
- 嚴重的骨刺。
- 懷孕。
- 感染、被確定對植入物或材料(質)過敏。
- 使用本產品螺釘治療骨質疏鬆病患時未使用骨水泥。

可能發生的不良影響：
手術醫師應在術前將可能發生之不良影響告知病患：
- 出血或血腫。
- 感染。
- 神經組織之併發症，麻痺。
- 植入物引起之疼痛、不適或異常感。
- 植入物彎曲、變形、移位、斷裂或鬆脫。
- 對植入物之金屬材質過敏。
- 植入物周圍出現金屬微屑。
- 延遲癒合或不癒合。
- 滑囊炎、皮膚潰爛或其他併發症。

- 未仔細切除椎間盤或將胸鎖乳突肌等肌肉復位，使神經根受壓迫或損傷。
- 脊椎癒合發生變化。

注意事項：
- 植入物需由曾經接受必要脊椎手術訓練之醫師施行植入，且符合適應症、禁忌症、不良反應及注意事項之敘述。
- 在臨床使用前，手術醫師需充分瞭解該手術之各個層面，及脊椎固定系統之限制，本產品宜由熟悉術前／後處置、手術技術、注意事項及此類手術可能風險的醫師施行。醫師對於手術技術、適宜的復位、植入物的選擇與安裝、術前／後的病患照護處置等知識是否充分，被視為手術療效成功與否之基本要素。
- 植入物尺寸適當、外形及材質都可能影響內固定器的穩固，因此正確選擇植入物非常重要，適當的植入物可將危險性降至最小，也因此植入物的尺寸、外形及材質強度都必須與人體骨骼相近才能達到最佳效果。
- 金屬材質的內固定器無法與正常、健康的骨骼具有相同的抗力，因此無法預判植入物在無輔助支撐的狀況下負荷身體重量時於何時損壞。
- 植入物可能因負荷過重而塌陷進而導致延遲癒合或不癒合，因此在骨癒合正常發生前，植入物必須以分擔負重方式承受負荷。
- 如延遲癒合或不癒合，植入物可能因金屬疲勞而縮短壽命。手術時植入物上的刮痕、磨損等都可能成為金屬疲勞提前發生的因素。
- 植入物須妥為保護，防止其與金屬或粗糙物體接觸而產生之損傷、刮痕、凹陷，上述變化會在表面層造成瑕疵及內部應力變化，而成為植入物斷裂之集中處。
- 混合使用不同材質金屬的植入物可能導致金屬腐蝕，如鈦質螺釘與不鏽鋼骨板相接合，將會導致不鏽鋼骨板腐蝕並迅速擴散、侵蝕骨板。腐蝕作用常導致植入物疲勞性斷裂，因此內固定器如螺釘與固定桿之材質必須一致或可相容，才不會引起腐蝕作用。建議史麥特歐美加脊椎固定系統不與其他材質或來源不明的製造廠之植入物混用。
- 植入物不得重複使用，植入物於移除後應立即予以拋棄。
- 手術過程中應使用X-Ray 及其他影像輔助定位、復位，以減少併發症。
- 史麥特歐美加脊椎固定系統包括固定桿、螺釘等植入物及一套特殊之配合器械組。除另有提示，不得使用其他器械，以免因兩者匹配性不良導致非預期之後果。

- 研究顯示吸煙患者之不癒合發生率較高，病患應被告知此項訊息及其潛在後果。
- 如病患之職業或活動會對植入物招致過度之應力，可能會導致植入物的失敗。
- 在某些案例中，退化性疾病之發展有可能過於迅速，以致減低植入物之預期使用壽命。 果真如此，骨科器材或植入物僅能視為一項延遲技術，或提供暫時性舒緩之裝置。
- 病患應當被充分告知植入物的限制，包含/不僅限於病患體重或活動之過度負荷所產生之衝擊，並須被教導合宜的控制自身活動。 病患應當清楚瞭解金屬植入物不如正常、健康的骨骼一般強壯，如過度負荷將導致植入物彎曲、變形、鬆脫或斷裂。病患如因活躍、虛弱或心智失常，以致無法使用重量支撐裝置，可能會在術後復健期間承受較大風險。
- 拔除未鬆脫之脊椎螺釘可能需要使用特殊器械破壞植入物表面介面，此項技術應於尚未臨床施行前先行實驗模擬操練之。
- 醫師於決定拔除植入物前，應將病患需再接受另一次手術之風險及拔除困難等因素列入考慮。
- 植入物拔除後須妥善照護，以防止骨折發生。

警告：
椎弓根固定系統之療效及安全性，僅限於脊椎出現不穩定及變形，而須施行融合術且輔以植入物之脊椎症狀下得到證實確認，這些症狀為：因脊椎滑脫所導致在胸椎腰椎、薦椎的重大不穩定或變形，且有明確神經損傷證據者、骨折、脫位、側彎、前彎、脊椎腫瘤及前次融合術失敗等，這些裝置用於其他症狀之療效及安全性，目前無法得知。當不同材質之滑桿做連接時，建議使用墊換器做連接。

清洗與滅菌：
- 脊椎固定系統中聚醚醚酮平滑桿及聚醚醚酮預彎滑桿產品出廠前已經過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。
- 出廠前已滅菌產品除外，所有植入物及器械應於滅菌前以超音波及蒸餾水清洗五分鐘以上， 禁止使用氫氧化鈉（燒鹼）。
- 避免使用具有腐蝕性或表面粗糙（如菜瓜布、金屬刷）之產品洗滌植入物或器械。
- 檢查器械以確認是在可正常操作之狀態。
- 滅菌指示：所有提供未滅菌植入物及器械皆需以蒸氣進行滅菌，遵照滅菌器製造廠之指示，並以符合院內規範之方法為之，以達到SAL10^{-6}以上之滅菌基準值。以下為建議方式與條件：

方法	蒸氣循環	溫度	滅菌時間	乾燥時間
高壓蒸氣	重力	121˚C/250˚F	30分鐘	30分鐘
高壓蒸氣	真空	132˚C/270˚F	4分鐘	30分鐘

包裝、標示與儲存：
- 脊椎固定系統中聚醚醚酮平滑桿及聚醚醚酮預彎滑桿產品已經過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。
- 史麥特歐美加脊椎固定系統之植入物與器械均以未滅菌方式供應。
- 植入物係置於包裝袋中分銷，在送達時植入物包裝及仿單必須是良好狀態方可驗收入庫，所有與此類植入物有關之法律資訊詳見袋內仿單標示。
- 植入物亦或以整組方式供應，置於特殊設計之收納箱內俾能直接滅菌。
- 處理及儲存植入物時需小心謹慎，將植入物裁剪、急劇折彎或刮傷植入物表面，均會明顯損及植入物的力學強度及抗疲乏強度，並導致裂紋及/或肉眼無法查覺的內部壓力，以致植入物斷裂。
- 植入物及器械皆應避免儲存於腐蝕性之環境中（如帶鹽分之空氣、潮濕等）。
- 建議在術前檢視植入物與器械，並模擬組裝，以分辨是否在儲存或前次手術中受損。

產品規格：

品名	噴砂處理	陽極處理
螺釘系列 單軸中空螺釘、 單軸中空長螺釘、 多角度中空螺釘、 多角度中空長螺釘 單軸側孔螺釘、 單軸側孔長螺釘 多角度側孔螺釘、 多角度側孔長螺釘	灰色	Ø 4.5mm_銀色
		Ø 4.75mm_桃紅色
		Ø 5.0mm_黃金色
		Ø 5.5mm_淺藍色
		Ø 6.0mm_綠色
		Ø 6.25mm_淡桃紅色
		Ø 6.5mm_藍色
		Ø 7.0mm_桃紅色
		Ø 7.5mm_淡桃紅色
		Ø 8.0mm_青銅色
		Ø 8.5mm_青藍色
		Ø 9.0mm_銀色
		Ø 10mm_淺藍色

品 名	噴砂處理	陽極處理
星型固定螺絲	灰色	銀色
六角固定螺絲		藍色

品 名	噴砂處理	陽極處理
橫向連接器	灰色	銀色

品 名	噴砂處理	陽極處理
固定式橫向連結器	灰色	黃色
可調式橫向連結器		藍色

品 名	噴砂處理	陽極處理
椎板鉤、椎弓根鉤、左脊椎鉤、 右脊椎鉤、連結塊、側邊桿、 滑桿、預彎滑桿(A)、 預彎滑桿(B)、變換器	灰色	銀色

規格詳如附表

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)