A-SPINE

Winloc Anterior Cervical Plate System Instructions for Use

English I-SFS-005-HE | 繁體中文 I-SFS-016-ET | 简体中文 I-SFS-007-FS

May 2024

C0101-Z-z10 V10

Manufacturer

A-SPINE

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EN

Winloc Anterior Cervical Plate System Instructions for Use

IMPORTANT NOTICE
The users of the Winloc Anterior Cervical Plate System acknowledge that they have read and agreed to the statement in this instruction, ensure that you are familiar with appropriate surgical technique.

DESCRIPTION
The Winloc Anterior Cervical Plate System consists of wide range of cervical plates and screws. The bone plate design can prevent screws from backing out and can be combined with expandable bone screws, enhancing stability of fixation and leading to improved therapeutic results. The instruments are designed for implantations of the Winloc Anterior Cervical plate system. The method of implanting is described in the Winloc Anterior Cervical Plate System Surgical Technique.

MATERIAL
All components of the Winloc Anterior Cervical plate system are made of Titanium alloy (Ti6Al4V, ASTM F136/ISO 5832-3), which are biocompatible, corrosion resistant, non-toxic under biological conditions and interferes as little as possible with imaging processes such as X-ray imaging and computer tomography.

INTENDED USE
The Winloc Anterior Cervical Plate System is intended for the anterior surgical stabilization of the cervical spine. The implant enables the immobilization of the fusion mass until consolidation of the implant or bone transplantation.

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

CONTRAINDICATIONS
- Patients with acute infection, whether superficial or deep
- Bony abnormalities, unable to ensure fixation of bone screws
- Pathological obesity
- Open wounds
- Patients with a history of material allergy or who tend to react to foreign bodies
- The physician must consider carefully before treating patients who are in a generally unfavorable medical or psychological state and who could be made worse by the procedure
- Pregnancy

WARNING AND PRECAUTIONS
- Appropriate size selection, material, shape, placement, and fixation play a 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 resistance of metallic internal fixation devices differs from that of healthy bones. Hence, it is difficult to anticipate the point of damage for the implant when subjected to body weight without supplementary support.
- Implants may collapse under excessive load, leading to delayed fusion or non-fusion. Therefore, the internal fixator must share the load until the physician verifies bone healing.
- Delayed or non-union healing may result in shortened lifespan of implants due to metal fatigue. The surgeons should avoid notching or scratching the implants which will contribute to early fatigue of the implants.
- Mixing metals or contact between dissimilar metal, such as titanium screws used with a stainless steel bone plate will accelerate the corrosion process of stainless steel. Therefore, devices that come into contact with each other should be made from similar or compatible metals.
- Implant should not be reused and should be discarded upon removal.
- Utilizing X-Ray during surgery for positioning and realignment is crucial in reducing complications.
- The surgeon must be thoroughly knowledgeable of the mechanical and metallurgical limitations of the Winloc Anterior Cervical Plate System implants. Adequate training, careful reading of the technical manual and experiences in the surgical technique is advised before using the Winloc Anterior Cervical Plate System.

- The patient's activity degree will have a significant impact on the useful life span of any temporary internal fixation devices. The Patient must be informed that any activity increases the risk of loosening, bending or breaking the device, especially before proper bone grafting and normal healing of bone tissue occurs.
- Correct handling of the implant is extremely important. Contouring of metal implants should only be performed with proper bending equipment.

POSSIBLE SIDE 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 metallic internal fixation devices. General surgical risks should be explained to the patient prior to surgery.

- The potential complications of spinal surgery may include: urological and reproductive dysfunction, gastrointestinal disturbances, vascular circulatory system dysfunction (including thrombosis), bronchial and pulmonary obstruction (including embolism), Bursitis, haemorrhage, myocardial infarction, infection, paralysis, or death.
- Injury to the dura mater and arachnoid mater caused by surgery. Peripheral nerve abnormalities, nerve injury, localized ossification, vascular and neural disorders.
- Pain, discomfort or abnormal sensations due to presence of the device.
- Improper installation, inflammation, premature loading, and trauma may result in loosening, bending, fracturing, or detachment of the implant.
- Sensitivity or allergic reaction to a foreign body
- Decrease in bone density due to stress shielding

- Delayed union, nonunion or pseudoarthrosis
- Sensitivity in skin or muscle patients could lead to skin ulceration or other complications
- Inadequate excision of intervertebral discs or failure to reposition muscles such as the sternocleidomastoid can cause compression or injury to the nerve roots
- In the case of a serious adverse event, additional surgery might be required

CLEANING & STERILIZATION
- All implants and instruments should be cleaned by ultrasonic cleaner with fresh cleaning solution for 10 minutes. Neutral or weakly alkaline cleaners are recommended to avoid the choice of detergents and disinfectants containing the following ingredients: strong organic acids, oxidizing acids, strong alkaline solutions, chlorine and iodine.
- 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.
- The implants and instruments are recommended to be sterilized with the A-SPINE designed trays and/or cases.
- 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 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.
- Be careful 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
- 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

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繁體中文

穩特頸椎前路骨板系統
Winloc Anterior Cervical Plate System

衛部醫器製字第004221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：
穩特頸椎前路骨板系統為一頸椎固定系統，材質為符合ASTM F136規範之鈦合金(Ti6Al4V ELI)製成，所使用之器械均針對植入物而特別設計，骨板之設計有特殊的螺釘防退出裝置，並可搭配可撐開骨螺釘，使固定更加穩固，並達到更佳之治療效果。

適應症：
- 退化性椎間盤突出。
- 半椎體或全椎體切除之椎孔減壓術。
- 椎體骨折與腫瘤切除後之固定。
- 脊柱畸形(前凸、後凸與側彎)。
- 假關節。
- 脊椎滑脫。
- 脊椎峽窄。
- 前次融合術失敗。

禁忌症：
- 椎體有活動期感染。
- 骨質異常不能確保骨螺釘之固定。
- 病態性肥胖症。
- 開放性創傷。
- 金屬過敏者。

注意事項：
- 植入物適當的尺寸、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塌陷，進而導致延遲癒合或不癒合，因此在醫師檢查確定骨癒合正常發生前，內固定器必須以分攤負重方式承受負荷。
- 如延遲癒合或不癒合，植入物可能因金屬疲勞而縮短壽命。而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。
- 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骨板的材質必須一致或可相容，才不會引起腐蝕作用。
- 植入物絕不可重複使用，已植入過的融合器於移除後應予銷毀拋棄。
- 手術過程中應使用X-Ray 輔助定位、復位，以減少併發症。
- 滅菌指示：所有植入物及器械皆需以蒸氣滅菌，遵照滅菌器製造商之指示（依滅菌器之種類及擬消毒之產品），並以符合院內規範之方法為之，以達到10^{-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

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：
- 脊椎手術可能之併發症包括：泌尿生殖功能紊亂、胃腸道功能紊亂、血管循環系統失調(包括血栓)、支氣管及肺的障礙(包括栓塞)、黏液囊炎、大出血、心肌梗塞、感染、癱瘓或死亡。
- 手術導致之硬脊膜硬腦脊膜的損傷。周圍神經病變、神經損傷、患部骨化、血管和神經障礙。
- 植入物引起疼痛、不適或異常感。
- 由於安裝不當、發炎、過早負重及創傷可能使植入物鬆動、彎曲、斷裂或鬆脫。
- 對植入物之金屬材質過敏。
- 因吸收或壓力遮蔽效應造成骨密度降低。
- 延遲癒合或不癒合和假關節。
- 敏感性皮膚或肌肉患者可能有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。
- 發生嚴重不良反應可能需要再次手術。

產品規格：
產品部分型號經陽極氧化處理，使其表面產生色差用以區別不同尺寸之型號，說明如下：

品名	噴砂處理	陽極處理
穩特頸椎骨板 WinLoc Plate	灰色	銀色

品名	尺寸	噴砂處理	陽極處理
穩特頸椎螺 Variable Self Drilling Screw	ψ4.0 mm	灰色	黃金色
穩特頸椎螺 Variable Self Tapping Screw	ψ4.0 mm	灰色	淺藍色
穩特頸椎螺 Variable Oversized Screw	ψ4.5 mm	灰色	桃紅色
穩特頸椎螺 Constrained Self Drilling Screw	ψ4.0 mm	灰色	銀色
穩特頸椎螺 Constrained Self Tapping Screw	ψ4.0 mm	灰色	綠色
穩特頸椎螺 Constrained Oversized Screw	ψ4.5 mm	灰色	藍色
穩特撐開螺釘 Expandable Screw	ψ4.0 mm	灰色	銀色

*規格詳如附表。

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，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)

簡体中文

颈椎前路固定系统 使用说明书

使用前请务必详阅原厂之使用说明书并遵照指示使用

医疗器械注册证编号：国械注许20143130169
产品技术要求编号：国械注许20143130169

产品性能：
颈椎前路固定系统为一颈椎固定系统，材质为符合ASTM F136规范之钛合金(Ti6Al4V ELI)制成，所使用之器械均针对植入物而特别设计，骨板之设计有特殊的螺钉防退出装置，并可搭配可撑开骨螺钉，使固定更加稳固，并达到更佳之治疗效果。

结构及组成：
本产品为非有源外科金属植入物，由骨板和骨钉组成，其中骨板由骨板主体和垫片两部分组成。本产品采用符合ASTM F136的钛合金材料制造，牌号为Ti6Al4V ELI。产品表面经阳极氧化处理，为非灭菌包装。

适用范围：
本产品用于退化性椎间盘突出、半椎体或全椎体切除的椎孔减压术、椎体骨折与肿瘤切除后的固定、脊柱畸形（前凸、后凸与侧弯）、假关节、脊柱滑脱、脊椎狭窄、前次融合术失败。

适应症：
- 退化性椎间盘突出。
- 半椎体或全椎体切除之椎孔减压术。

- 椎体骨折与肿瘤切除后之固定。
- 脊柱畸形(前凸、后凸与侧弯)。
- 假关节。
- 脊椎滑脱。
- 脊椎峡窄。
- 前次融合术失败。

禁忌症：
- 椎体有活动期感染。
- 骨质异常不能确保骨螺钉之固定。
- 病态性肥胖症。
- 开放性创伤。
- 金属过敏者。

注意事项：
- 植入物适当的尺寸、外形及材质都可能影响内固定器的稳固，因此正确选择植入物非常重要，适当的植入物可将危险性降至最小，也因此植入物的尺寸、外形及材质强度都必须与人体骨骼相近才能达到最佳效果。
- 金属材质的内固定器无法与正常、健康的骨骼具有相同的抗力，因此无法预判植入物在无辅助支撑的状况下负荷身体重量时于何时损坏。
- 植入物可能因负荷过重塌陷，进而导致延迟愈合或不愈合，因此在医师检查确定骨愈合正常发生前，内固定器必须以分担负重方式承受负荷。
- 如延迟愈合或不愈合，植入物可能因金属疲劳而缩短寿命。而手术时植入物上的刮痕、磨损等都可能成为金属疲劳提前发生的因素。

- 混合使用不同材质金属的植入物可能导致金属腐蚀，如钛质螺钉与不锈钢骨板相接合，将会导致不锈钢骨板腐蚀并迅速扩散、侵蚀骨板。腐蚀作用常导致植入物疲劳性断裂，因此内固定器如螺钉与骨板的材质必须一致或可兼容，才不会引起腐蚀作用。
- 植入物绝不可重复使用，已植入过的融合器于移除后应予销毁抛弃。
- 手术过程中应使用X-Ray 辅助定位、复位，以减少并发症。
- 灭菌指示：所有植入物及器械皆需以蒸气灭菌，遵照灭菌器制造商之指示（依灭菌器之种类及拟消毒之产品），并以符合院内规范之方法为之，以达到10^{-6}以上之灭菌基准值。以下为建议方式与条件：

  方法　蒸气循环　温度　　灭菌时间
  1. 高压蒸气　重力　121℃/ 250℉　30分钟
  2. 高压蒸气　重力　134℃/ 273℉　20分钟
  3. 高压蒸气　真空　132℃/ 270℉　4分钟

警示：
手术医师应在术前将可能发生之不良影响告知病患：
- 脊椎手术可能之并发症包括：泌尿生殖功能紊乱、胃肠道功能紊乱、血管循环系统失调(包括血栓)、支气管及肺的障碍(包括栓塞)、黏液囊炎、大出血、心肌梗塞、感染、瘫痪或死亡。
- 手术导致之硬脊膜硬脑脊膜的损伤。周围神经病变、神经损伤、患部骨化、血管和神经障碍。
- 植入物引起疼痛、不适或异常感。
- 由于安装不当、发炎、过早负重及创伤可能使植入物松动、弯曲、断裂或松脱。
- 对植入物之金属材质过敏。
- 因吸收或压力遮蔽效应造成骨密度降低。
- 延迟愈合或不愈合和假关节。
- 敏感性皮肤或肌肉患者可能有皮肤溃烂或其他并发症。
- 未仔细切除椎间盘或将胸锁乳突肌等肌肉复位，使神经根受压迫或损伤。
- 发生严重不良反应可能需要再次手术。

产品维护和保养方法：
植入物不得重复使用，植入物于移除后应立即予以抛弃。如发现包装破损可向本公司提出更换。

储存、运输条件方法：
常温，勿重压，组织调配单位有责任维持植入前的适当贮存状态。

生产日期/失效日期:见产品简体标签内容

注册人/生产企业
名称：冠亚生技股份有限公司
企业住所：新北市永和区成功路一段80号20楼
生产地址：新北市新店区复兴里复兴路43号（1楼）
联系方式：886-2-2926-7088

代理人/售后服务机构
名称：新联医疗用品（淄博）有限公司
住所：山东省淄博市高新区尊贤路2999号新华联合3楼B302
电话：0533-7868788

医疗器械外包装所用符号的说明：

符号	说明	符号	说明
NON STERILE	未灭菌	LOT	批次代码
	警告		生产日期
	有效期		不得二次使用
	查阅使用说明	/	/

说明书的修订日期：2024年04月08日
附表为颈椎前路固定系统的规格型号表

颈椎前路固定系统型号规格表

表1颈椎骨板型号规格表　　单位：mm

产品型号	描述	宽 W	长 L	孔径允差 0~+0.2
1468-208N	稳特颈椎骨板	16	20	4.5
1468-238N		16	23	4.5
1468-258N		16	25	4.5
1468-268N		16	26	4.5
1468-278N		16	27	4.5
1468-288N		16	28	4.5
1468-308N		16	30	4.5
1468-328N		16	32	4.5
1468-338N		16	33	4.5
1468-348N		16	34	4.5
1468-368N		16	36	4.5
1468-388N		16	38	4.5
1468-398N		16	39	4.5
1468-408N		16	40	4.5
1468-428N		16	42	4.5
1468-448N		16	44	4.5

表1（续）　　单位：mm

产品型号	描述	宽 W	长 L	孔径允差 0~+0.2
1468-458N	稳特颈椎骨板	16	45	4.5
1468-468N		16	46	4.5
1468-488N		16	48	4.5
1468-508N		16	50	4.5
1468-518N		16	51	4.5
1468-528N		16	52	4.5
1468-548N		16	54	4.5
1468-568N		16	56	4.5
1468-588N		16	58	4.5
1468-608N		16	60	4.5
1468-628N		16	62	4.5
1468-648N		16	64	4.5
1468-668N		16	66	4.5
1468-688N		16	68	4.5
1468-708N		16	70	4.5
1468-728N		16	72	4.5
1468-748N		16	74	4.5

表1（续）　　单位：mm

产品型号	描述	宽 W	长 L	孔径允差 0~+0.2
1468-768N	稳特颈椎骨板	16	76	4.5
1468-788N		16	78	4.5
1468-808N		16	80	4.5
1468-828N		16	82	4.5
1468-848N		16	84	4.5
1468-868N		16	86	4.5
1468-888N		16	88	4.5
1468-908N		16	90	4.5
1468-928N		16	92	4.5
1468-948N		16	94	4.5
1468-968N		16	96	4.5
1468-988N		16	98	4.5
1468-008N		16	100	4.5
1468-028N		16	102	4.5
1468-048N		16	104	4.5
1468-068N		16	106	4.5

表2颈椎螺钉型号规格表　　单位：mm

产品型号	描述	螺纹外径 0.15~0	长 L
1450-128N	稳特颈椎螺钉	4.00	12
1450-138N		4.00	13
1450-148N		4.00	14
1450-158N		4.00	15
1450-168N		4.00	16
1450-178N		4.00	17
1450-188N		4.00	18
1450-208N		4.00	20
1450-228N		4.00	22
1450-248N		4.00	24
1450-268N		4.00	26
1451-128N		4.00	12
1451-138N		4.00	13
1451-148N		4.00	14
1451-158N		4.00	15
1451-168N		4.00	16
1451-178N		4.00	17
1451-188N		4.00	18

表2（续）　　单位：mm

产品型号	描述	螺纹外径 0.15~0	长 L
1451-208N	稳特颈椎螺钉	4.00	20
1451-228N		4.00	22
1451-248N		4.00	24
1451-268N		4.00	26
1452-128N		4.50	12
1452-138N		4.50	13
1452-148N		4.50	14
1452-158N		4.50	15
1452-168N		4.50	16
1452-178N		4.50	17
1452-188N		4.50	18
1452-208N		4.50	20
1452-228N		4.50	22
1452-248N		4.50	24
1452-268N		4.50	26
1453-128N		4.00	12
1453-138N		4.00	13
1453-148N		4.00	14

表2（续）　　单位：mm

产品型号	描述	螺纹外径 0.15~0	长 L
1453-158N	稳特颈椎螺钉	4.00	15
1453-168N		4.00	16
1453-178N		4.00	17
1453-188N		4.00	18
1453-208N		4.00	20
1453-228N		4.00	22
1453-248N		4.00	24
1453-268N		4.00	26
1454-128N		4.00	12
1454-138N		4.00	13
1454-148N		4.00	14
1454-158N		4.00	15
1454-168N		4.00	16
1454-178N		4.00	17
1454-188N		4.00	18
1454-208N		4.00	20
1454-228N		4.00	22

表2（续）　　单位：mm

产品型号	描述	螺纹外径 0.15~0	长 L
1454-248N	稳特颈椎螺钉	4.00	24
1454-268N		4.00	26
1455-128N		4.50	12
1455-138N		4.50	13
1455-148N		4.50	14
1455-158N		4.50	15
1455-168N		4.50	16
1455-178N		4.50	17
1455-188N		4.50	18
1455-208N		4.50	20
1455-228N		4.50	22
1455-248N		4.50	24
1455-268N		4.50	26