KINAMED®
INCORPORATED

Kinamed, Inc.
820 Flynn Road
Camarillo, CA 93012
(800) 827-5775
(805) 384-2792 (Fax)
www.kinamed.com

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INFORMATION CONCERNING USE OF THE KINAMED ISO-ELASTIC™ CERCLAGE SYSTEM

Protected by U.S. Patent No. 6,589,246. Other U.S. and International Patents Pending.

GENERAL REMARKS

This brochure is a general operative guide for attachment and implantation of the Kinamed Iso-Elastic™ Cerclage polymer cable.

The Kinamed Iso-Elastic™ Cerclage System consists of a braided cerclage cable and attached metal clasp (Figure 1). The cable is flexible and possesses high fatigue and tensile strength.

The cable is made from biocompatible materials, consisting of UHMWPE strands braided over a nylon core. The clasp components are made from either stainless steel, titanium, or cobalt-chromium alloy (each package label states the material used for the enclosed clasp).

The general principles of patient selection and sound surgical judgment apply to the cerclage procedure.

PACKAGING and LABELING

See Product Label for information regarding the specific product referenced in this document. The implant should be accepted only if received by the hospital or surgeon with the factory packaging and labeling intact.

INDICATIONS

- Repair of long bone fractures due to trauma or reconstruction,
- Reattachment of the greater trochanter in total hip arthroplasty, surface replacement arthroplasty, or other procedures involving trochanteric osteotomy,
- Sternotomy Closure,
- Sublaminar and intrafacet wiring of the spinal column.

CONTRAINDICATIONS

- Active or suspected infection, either systemic or localized, in or around the implant site,
- Patient conditions, mental or neurological, that would tend to impact the patients ability to follow physician's instructions during the post-operative healing phase,
- Skeletally immature patients,
- Comprised vascularity that would inhibit adequate blood supply to the fracture or operative site,
- Insufficient quality or quantity of bone, which would inhibit rigid device fixation,
- Any disease affecting the support and fixation of the prosthesis,
- Distant foci of infection, such as genitourinary, pulmonary, skin or other sites which may spread to the implant site. The foci of infection should be treated prior to, during, and after implantation.

STERILITY

Cable and clip are supplied sterile. The package should be examined prior to use for possible breaks in the sterile barrier. Cable contains polyethylene and nylon polymers.

Do not autoclave or re-sterilize implants.

The cable-tensioning instruments are provided non-sterile and must be sterilized prior to surgical use per one of the following validated procedures:

Prevacuum: Wrapped, 3 – 3.5 minutes, 134 °C – 137 °C
Gravity: Wrapped, 30 minutes, 15 psi (103 kPa), 121 °C minimum
Gravity: Unwrapped, 15 minutes, 15 psi (103 kPa), 121 °C minimum

The instrument must be thoroughly cleaned prior to autoclaving.

PRECAUTIONS

The patient must be advised of the short and long term limitations of the procedure and the need to protect the implant from full weight bearing until adequate fixation and healing have occurred. Excessive activity and trauma affecting the reattachment and/or fixation have been implicated in failure of this procedure by loosening, fracture, and/or wear of the implants. Loosening of the components can result in increased production of wear particles, as well as damage to the bone, making successful revision surgery more difficult. The patient should be cautioned to limit activities, protect the bone from unreasonable stresses, and to follow the instructions of the physician with respect to follow-up care and treatment. The patient should be warned of the surgical risks, and made aware of possible adverse effects.

The patient should be warned that the device cannot and will not replicate the flexibility, strength, reliability or durability of normal healthy bone, that the implant can break or become damaged, particularly as a result of strenuous activity or trauma, and that the device has a finite expected service life and may need to be replaced in the future.

Transient bacteremia can occur in daily life. Dental manipulation, endoscopic examination, and other minor surgical procedures have been associated with transient bacteremia. To prevent infection at the implant site, it may be advisable to use antibiotic prophylaxis before and after such procedures.

An implant should never be re-used. Even though an implant may appear undamaged, previous handling and in-service stresses may have created imperfections that would reduce the service life of the implant.

Over-tensioning can create the potential for the cable to cut into the bone. Under-tensioning can cause inadequate fixation and increased fatigue stress. Improperly installed cable clips can cause cable loosening. Excessively long cable ends caused by not cutting the cable flush against the clip may result in bursitis.

Proper handling of any implant is mandatory. Prior to surgical use, a visual inspection of each implant for possible imperfections should be performed. Damaged or altered implants may produce undesirable stresses and cause defects which could lead to failure.

⚠ **CAUTION**

This document sets forth recommended procedures for using Kinamed devices and instruments. It offers guidance, but, as with any technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustment as necessary.

⚠ **CAUTION**

Federal Law restricts this device to sale by or on the order of a licensed physician.

WARNINGS

Improper placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. The surgeon is to be thoroughly familiar with the surgical procedure, instruments and implant characteristics prior to performing surgery.

Periodic, long-term follow-up is recommended to monitor the position and state of the implants, as well as the condition of the adjoining bone.

Patients should be questioned regarding sensitivity to metals. If there is a question pertaining to the patient's tolerance for titanium, stainless steel, or cobalt chrome appropriate testing should be performed.

The following conditions, singularly or concurrently, tend to impose severe loading on the affected bone, thereby placing the patient at higher risk for failure: obesity, heavy labor, active sports participation, high general activity level, likelihood of falls, alcohol or drug addiction, and other disabilities.

Some of the alloys used to produce orthopaedic implants contain metallic elements that may be carcinogenic in tissue cultures or intact organisms under unique circumstances. Questions have been raised in the scientific literature as to whether or not these alloys themselves may be carcinogenic in implant recipients. Studies conducted to evaluate this issue have not identified convincing evidence of such phenomenon, in spite of the millions of implants in use.

Polyethylene wear has been reported following implantation of many devices. Higher rates of wear may be initiated by metallic particles or other debris which can cause abrasion. Higher rates of wear likely will shorten the useful life of the device, and lead to an earlier than desired revision to replace the worn components.

Cerclage cable breakage is reported in the literature. Possible causes of breakage include, but are not limited to, over tensioning the cable, fretting, and delayed or non-union of the fracture, osteotomy, or fusion site. In many instances, adverse effects may be clinically related rather than implant related.

The surgical and post-operative management of the patient must be carried out with due consideration for all existing conditions of increased risk. Mental attitudes or personality disorders resulting in patient's failure to adhere to his/her physician's orders might delay post-operative recovery and aggravate adverse effects.

POST-OPERATIVE PROCEDURES

Late postoperative complications can include:

Early, or late loosening, wear, and change in position of one or more components.

•Trochanteric avulsion as a result of excess muscular tension, early weight bearing, or inadvertent intraoperative weakening.

•Trochanteric nonunion due to inadequate reattachment and/or early weight bearing.

•Progressive bone resorption and osteolysis.

The patient should be cautioned to govern his/her activity level. Postoperative therapy should be structured to prevent excessive loading.

The patient should be released from the hospital with complete instructions and warnings (preferably written) regarding further exercises and therapies. The patient should be encouraged to report any unusual changes to his/her physician.

CLEANING and MAINTENANCE of INSTRUMENTS

Flush the instrument thoroughly with sufficient water and cleaning agent to remove blood and other material.

Turn knob of tensioning instrument counterclockwise to fully open the grasping jaws. Flush instrument, including jaws, to clear any debris.

Next, turn knob of tensioning instrument clockwise to fully expose remainder of threads on the lead screw. Flush instrument again to clear any debris.

Prior to autoclave sterilization, apply a surgical grade lubricant to the threads and the jaw mechanism. Be sure that the lubricant fully penetrates the mechanism.

CARE and HANDLING

Use extreme care in handling and storage of implant components. Cable and clip must be handled with care. Twisting, kinking, cutting, notching, or scratching the braided surface may reduce the strength, fatigue resistance and/or wear characteristics of the implant system. These, in turn may induce internal stresses that are not obvious to the eye and may lead to fracture of the component. Implants and instruments should be protected during storage from corrosive environments, such as salt air, etc.

Only instruments designed for use with this system should be used to assure correct implantation. Review of these handling instructions is important. Damaged instruments may lead to improper cable tension or implant position and result in implant failure. Thorough familiarity with the surgical technique is essential to ascertain their proper working condition.

ADVERSE EFFECTS

With all implants, asymptomatic localized progressive bone resorption (osteolysis) may occur around or remote from the prosthetic components as a consequence of foreign body reactions to particulate matter. Particulate matter is generated by the interaction between implant components, as well as between the component and bone, primarily through wear mechanisms of adhesion, abrasion, and fatigue. Osteolysis can lead to future complications necessitating the removal and replacement of prosthetic components.

Although rare, metal sensitivity reactions in patients following device implantation have been reported. Implantation of foreign material in tissues can result in cellular reactions involving lymphocytes, macrophages and fibroblasts.

Early, or late loosening, cracking, fracture or deformation of one or more components. This is often attributable to factors listed under "WARNINGS." Loosening may also occur due to defective fixation or improper positioning.

Early or late infection, which may require removal of the implant.

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Kinamed 有限公司

CE 0086

美国加州 Camarillo 市 Flynn 路 820 号
邮编 93012
1-800-827-5775 （传真）1-805-384-2792
www.kinamed.com

SuperCable™ Iso-Elastic™ 环扎系统 B00109C

欧洲授权代表：

EC REP Europe Sarl.
11， rue Emile Zola B.P. 2332
F-38033 Grenoble Cedex 2. 法国
电话：+33 (0) 4 76 86 43 22
传真：+33 (0) 4 76 17 19 82

SUPERCABLE™ ISO-ELASTIC™ 环扎系统使用说明书：本产品受第 6,589,246 号美国专利保护。其他的美国和国际专利正在申办当中。

概述：本说明书为 SuperCable™Iso-Elastic™ 环扎聚合物线缆使用的通用指南。该系统由编织状的环扎线缆和金属锁扣组成。线缆具有良好的柔韧性、高度的抗疲劳性和较强的张力特性。本产品采用生物相容性材料制成，外层由编织成束的超高分子量聚乙烯包绕，内部线芯为尼龙。金属锁扣的材料为不锈钢、金属钛或者钴-铬合金三种材料中的任意一种（内置锁扣的材料在包装标签上均已注明）。病人选择和正确的手术判断中使用的基本原则也适用于环扎系统。

包装和标签：本文中所涉及的具体产品信息可参见产品标签。只能使用医院或外科医生认可的原厂包装、标签完整的植入物。

警告：联邦法律规定，唯有执照注册的医师方可购买或订购该产品。

适应症：(1)外伤引起的长骨骨折修复或者重建；(2)全髋关节成形术中的大转子复置、关节表面成形术、或者其他涉及转子骨切开的手术；(3)胸骨切开术的闭合；(4)脊柱的椎板下和椎间小关节的捆绑术。

禁忌症：(1)在植入部位或周围存在活动性感染或有疑似感染，包括全身感染或局部感染；(2)病人在心理上或神经系统方面，存在着不能遵从医嘱完成术后复原的倾向；(3)骨骼发育不成熟的患者；(4)病变的血管分布抑制骨折或者手术部位的供血，造成供血不足；(5)骨质量不佳及数量不足，导致本装置不能牢固固定；(6)任何影响术后植入物支持和固定的疾病；(7)远离植入部位的感染病灶，例如泌尿生殖器、肺部、皮肤或者其他部位，这些部位的感染可能扩散到植入部位。应该在线缆植入手术前、术中和术后对感染病灶进行治疗。

灭菌处理：环扎线缆和锁扣为无菌产品。在使用前应该检查包装内的消毒屏障有无破损。环扎线缆为聚乙烯和尼龙聚合物。**植入产品不能高压灭菌或者重复灭菌。**

线缆手术工具不是无菌产品，在手术前必须按照下列程序之一对其进行灭菌消毒：(1)预真空：包裹，3-3.5 分钟，134 ℃-137 ℃；(2)重力式灭菌：包裹，30 分钟，15 psi（103 kPa），最低温度 121 ℃；(3)重力式灭菌：不包裹，15 分钟，15 psi（103 kPa），最低温度 121 ℃。在高压灭菌前，必须将手术工具彻底清洁并上润滑油。

术前注意事项：必须告知患者手术后有短期和长期的活动限制，在线缆充分固定和愈合前要避免手术部位大量负重，以保护植入假体。过度活动和创伤可能造成植入物松动、断裂或者磨损，影响线缆的附着和/或者固定，导致手术失败。锁扣和线缆的松动可以增加磨损颗粒的产生，同样会损伤骨骼，并增加手术修复难度。应该告诫患者限制活动，保护骨骼避免承受不合理的外力，并且要在医生的指导下进行术后护理和治疗。应该告诉患者手术存在的风险和潜在的副作用。应该告诫患者本产品的柔韧性、强度、可靠性或耐久性不可能、也达不到原有正常健康骨骼的程度，特别在剧烈活动或者创伤时，该植入物可能断裂或者损坏；并且该产品的使用寿命有限，将来可能还需要更换。日常生活中可能发生一过性菌血症。如牙科手术、内窥镜检查和其他可能导致一过性菌血症的小手术。为了保护植入部位免受感染，建议在术前和手术后使用抗生素预防。

植入物均不可重复使用。即使使用过的植入物表面没有损坏的迹象，但在操作和使用过程中所受到的外力可能缩短其使用寿命，使产品产生缺陷。线缆张力过度可能导致线缆嵌入骨骼。张力不够可能导致固定不良和增加线缆的疲劳应力。锁扣安装不正确可引起线揽松动。应该剪掉锁扣外多余的线缆，否则线缆末端过长可以导致滑囊炎。必须正确操作植入物。在手术前，应该目视检查每一件植入物是否存在潜在的缺限。植入物损坏或者发生变化，可能产生不需要的应力和产品缺陷，并导致手术失败。

警告：该产品不适当的放置、定位和固定将导致

产品处于不正常的应力状态，这将缩短植入物的使用寿命。在使用线缆导向器和其他工具时应小心仔细，避免损伤神经血管组织。在固定和拉紧线缆时要格外小心，以避免碰伤或系住神经血管组织，并因此产生一系列后遗症。手术前，医生应彻底熟悉手术操作过程，手术工具和植入物的特性。建议定期、长期随访病人，随时检查植入物的位置和状况，以及邻近骨骼的状况。应该询问患者对金属有无过敏。如果患者存在对钛、不锈钢、或者钴铬合金的耐受性问题，应该进行相关的试验。患者存在下列一项、或几项因素时，例如：肥胖、重体力劳动、剧烈的体育活动、高强度活动、跌倒、酗酒或者药物成瘾，以及其他残疾，将使骨骼承受严重的外力，从而使手术处于失败的高风险中。有些矫形植入物的合金包含一些金属元素，在特定的情况下，这些元素在组织培养物或者有机体中可能表现出致癌性。植入体内的合金本身对人体是否致癌的讨论已见诸科学文献。尽管已经实施了数百万例的临床手术，但该问题的研究还缺乏具有说服力的证据。临床上已有植入后聚乙烯发生磨损的报道。金属颗粒或者骨碎片会导致磨损，从而增加磨损率。高磨损率将缩短线缆的使用寿命，导致要提早更换组件。文献中已有环扎线缆断裂的报道。可能的原因包括但不局限于以下几点：线缆张力过度、微振磨损以及骨折、截骨术或者融合部位的延迟愈合或者不愈合。在很多情况下，愈后不良可能与临床情况有关，而不是植入物本身的问题。在术中和术后的护理中，必须充分考虑患者的现有情况，这些情况有可能增加手术风险。患者不能遵守医嘱的心理状态或性格失调，可能延长手术后的恢复期和加重副作用。

术后处理：晚期术后并发症包括：(1)早期或晚期的线揽松动、磨损，以及单个或者多个植入物位置变化。(2)由于肌肉过度紧张、早期负重或者术中不利的疏忽，导致转子撕裂。(3)由附着不良和/或者早期负重造成的转子不愈合。(4)进行性骨吸收和骨溶解。应该告诫患者限制活动强度。手术后理疗要有医生指导，防止病人负荷过度。

关于患者出院后的活动和治疗方案，医生应该提供全面详细的指导和列出（最好书面形式的）警告事项。应该鼓励病人及时向医生报告一切出现的异常情况。

手术工具的清洁和维护：用足量的水和清洁剂彻底冲洗手术工具，清除血液和其他物质。逆时针旋转张力器的扳手，完全张开钳口。冲洗包括钳口在内的手术工具，以清除任何残留物。下一步，旋转张力器的旋钮，完全暴露出螺杆上的螺纹。再次冲洗手术工具，以清除任何残留物。

在高压灭菌之前，在螺纹和钳口机械装置上涂抹手术级的润滑剂。并确保润滑剂完全渗入到机械装置内部。

保管和搬运：在搬运和存放植入物时必须非常小心。必须轻拿轻放线缆和金属锁扣。扭曲、打结、切断、划刻或者擦伤编织物表皮都可能降低植入物的强度、抗疲劳性和/或者耐磨损特征。结果可能诱发肉眼不易识别的内部应力，并且可能导致组件的断裂。在存放期间应该使植入物和手术工具远离腐蚀性环境，比如空气中含盐量高的地方等。只有使用本系统专用的手术工具，才能确保植入正确。反复阅读操作说明非常重要。手术工具的损坏可以造成线缆张力不足或者位置不当，导致植入失败。若想了解整个系统是否处在正常工作状态，必须彻底熟悉整个手术环节。

副作用：所有植入物，在植入部位周围或者远端都会产生局部无症状的进行性骨吸收（骨溶解），这是颗粒物质的异物反应结果。颗粒物质是植入物本身，以及植入物和骨骼之间的相互作用而产生的，这种相互作用主要通过粘附、磨擦和疲劳产生机械磨损。骨质溶解可能引起进一步的并发症，到时需要取出和更换植入物。

患者在装入植入物后，对金属产生过敏反应的病例虽然罕见，但临床上也有报道。外源性材料植入组织以后，可以导致涉及淋巴细胞、巨噬细胞和成纤维细胞的细胞反应。单个或者多个组件可能会发生的早期或者晚期松动、裂缝、破裂或者变形，通常属于上文“警告”一栏中所列的事项。线缆松动也可能由于固定不牢或者定位不准引起。若发生早期或者晚期感染，可能需要取出植入物。

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中国总代理
艾文泰 （上海）商业有限公司
电话：021－58764441
传真：021－58764441
网站：www.avantech-sh.com
上海市浦东新区张杨路 158 号 1610 室 200122