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SuperCable® Iso-Elastic™ Cerclage System
(1mm and 2mm Cable Diameters)
Instructions for Use

INFORMATION CONCERNING USE OF THE SUPERCABLE® ISO-ELASTIC™ CERCLAGE SYSTEM. Protected by U.S. Patent Nos. 6,589,246, 7,207,090, 8,469,967, 9,107,720. Japan Patents 4,829,236, 5,938,095. EU Patents 1,389,940, 1,781,961, 2,432,401, 3,013,268. Turkey Patents TR201309922T4, TR201405440T4. Other U.S. and International Patents Pending.

GENERAL REMARKS: This brochure is a general operative guide for implantation of the Kinamed SuperCable® Iso-Elastic™ Cerclage polymer cable system. The Kinamed SuperCable Iso-Elastic™ Cerclage System consists of a braided cerclage cable and attached metal clasp. 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 titanium alloy per ISO 5832-3 and ASTM F136. The braided cable is available in a diameter of either 1mm or 2mm. Refer to the device product label for identification of clasp material, cable diameter, and corresponding part number for the device enclosed. 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.

Do not use if package is damaged.

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 adjustments as necessary.

CAUTION

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

Devices labeled for single use are intended to be used once only, for a single patient, because they may not perform as intended if they are reused. Reuse may lead to failure of the device to perform as intended.

MR SAFETY INFORMATION

Location of Use	MR Safety Information
Within the USA	The SuperCable implant has not been tested for safety and compatibility in the MR environment (it has not been tested for heating, migration, or image artifact in the MR environment).
Outside the USA	The SuperCable implant has been evaluated for safety and compatibility in the MR environment and determined to present a low risk for heating, migration, and image artifact.

INDICATIONS: (1) Repair of long bone fractures due to trauma or reconstruction; (2) Reattachment of the greater trochanter in total hip arthroplasty, surface replacement arthroplasty, or other procedures involving trochanteric osteotomy; (3) Sternotomy Closure.

CONTRAINDICATIONS: (1) Active or suspected infection, either systemic or localized, in or around the implant site; (2) Patient conditions, mental or neurological, that would tend to impact the patients ability to follow physician's instructions during the post-operative healing phase; (3) Skeletally immature patients; (4) Compromised vascularity that would inhibit adequate blood supply to the fracture or operative site; (5) Insufficient quality or quantity of bone, which would inhibit rigid device fixation; (6) Any disease affecting the support and fixation of the prosthesis; (7) 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 clasp 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 cable implants.

The reusable SuperCable instruments are provided in non-sterile condition and are intended to be steam sterilized by the end user prior to surgical use. Inspect instruments for dryness prior to sterilization.

Location of Use	Method	Cycle Type	Sterilization Temperature	Exposure Time[2]	Dry Time
Within the USA	Steam Autoclave Double Wrapped[1]	Pre-vacuum	132°C (270°F) Minimum	4 Minutes Minimum	60 Minutes Minimum
Outside the USA	Steam Autoclave Double Wrapped[1]	Pre-vacuum	134°C (273°F) Minimum	3 Minutes Minimum	60 Minutes Minimum

[1] Validated with KimGuard® KC600.
(Validated to the following standards: ISO 17665-1:2006 and ANSI/AAMI ST79-2010)
[2] This is the exposure time only, it does not represent the total cycle time.

The reusable instruments should be visually inspected for wear and tear, routinely and prior to each surgical use. Visual inspection should be performed to look for imperfections or deterioration (such as corrosion, pitting, significant discoloration, cracking, breakage, disassembly, etc.). For reusable instruments that show evidence of such deterioration, the user should first contact Kinamed (or, for users located outside the USA, the authorized Kinamed distributor) to determine if repair is possible. If Kinamed determines that repair is possible, the user should thoroughly clean the deteriorated reusable instrument before returning for repair. If Kinamed determines that repair is not possible, then the deteriorated reusable instrument may be discarded using the hospital's normal disposal procedure for similar types of surgical instruments. Note that it is normal and expected for anodized instrument surfaces to show slight discoloration after repeated cleaning and sterilization cycles. Such discoloration is not evidence of deterioration.

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 clasps 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

Cable and locking clasp may be re-tensioned and re-locked as necessary. If a locked cable must be removed from or relocated on the bone, it can be cut and discarded, and a new cable applied in the desired location. Alternatively, cable tension can be relieved by unseating the locking wedge with dedicated instrumentation. Intentional unseating of the wedge should be performed a maximum of once per cable.

WARNINGS: Improper placement, positioning and fixation of these devices may result in unusual stress conditions reducing the service life of the implant. Use care in utilizing the cable passer and other instrumentation to avoid damaging neurovascular structures. Exercise caution when positioning and tightening the cerclage cables to avoid impinging or tethering neurovascular structures and causing attendant significant sequelae. 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.
The SuperCable reusable cable passer instruments contain chemicals, including formaldehyde, known in the state of California to cause cancer.

POST-OPERATIVE PROCEDURES: Late postoperative complications can include: (1) Early or late loosening, wear, and change in position of one or more components; (2) Trochanteric avulsion as a result of excess muscular tension, early weight bearing, or inadvertent intra-operative weakening; (3) Trochanteric non-union due to inadequate reattachment and/or early weight bearing; (4) 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.

RECOMMENDED CLEANING of NON-STERILE INSTRUMENTS: (Validated to NHS Health Technical Memoranda HTM2030 – Washers and HTM2010 – Sterilizers)

Pre-process Handling: Remove gross soiling by submerging the instrument into cold tap water immediately after use. Instruments should be cleaned within 30 minutes of use to minimize the potential of staining, damage, and drying.

(1) Manual Soak: Completely submerge instruments in neutral pH enzymatic detergent (i.e. Ruhof Endozime® AW Triple Plus®, dilute 1/2 ounce per one (1) gallon (4ml/liter) of warm (20-25°C) tap water) for 5 minutes. Use a soft bristled, nylon brush to gently scrub the device until all visible soil has been removed. Particular attention should be given to hard to clean areas. Visually inspect the instruments for cleanliness and repeat the manual soak step (1) until no visual contamination is present. For reusable instruments that are not visually clean after multiple attempts to repeat the manual cleaning cycle, the user may discard the instrument using the hospital's normal disposal procedure for similar types of surgical instruments. Note that it is normal and expected for anodized instrument surfaces to show slight discoloration after repeated cleaning and sterilization cycles. Such discoloration is not evidence of visual contamination.

Manual Rinse: Remove instruments from the enzymatic solution and rinse thoroughly under running Deionized (DI) water for a minimum of 1 minute. Thoroughly and aggressively brush and flush through cannulated areas using a DI water jet with the exit end submerged for a minimum of 1 minute. Turn knob of tensioning instrument to fully expose remainder of threads on the lead screw. Flush instrument for a minimum of 2 minutes with DI water again to clear any debris.

(2) Combination Manual/Automated Soak and Rinse: Same as manual soak and rinse in section **(1)** above. **Washer/Dryer:** Place instruments in a suitable washer basket and load in an automatic washer/dryer. Cycle should be set for a Non Caustic wash cycle according to the table below.

Phase of Automatic Cycle:	Minimum Water Quality / Temperature	Minimum Time	Detergent / Dilution
Pre-Rinse	Tap Water / 21°C	4 minutes	N/A
Wash	Tap Water / 56°C	14 minutes	Ruhof Endozime® AW Triple Plus®, pour directly into detergent reservoir at full strength or set the dispenser to 1/2 ounce per one (1) gallon (4ml/liter) of warm (20-25°C) tap water
Rinse	Tap Water / 58°C	1 minute	N/A
Final Rinse - Thermal Disinfectant Rinse	DI Water / 93°C	1 minute	N/A
Dry	N/A / 95°C	27 minutes	N/A
Total Cycle Time	N/A	70 minutes	N/A

MAINTENANCE of REUSABLE INSTRUMENTS: Prior to autoclave sterilization, apply a surgical grade lubricant to the tensioner threads and the wedge insertion cam mechanism of the tensioning instrument. Be sure that the lubricant fully penetrates the mechanism. Wipe any excess lubricant that may have been deposited on the back of the instrument body. **Extreme care should be exercised lubricating this thread to prevent any excess lubricant from depositing in the cable holding grooves.**

⚠ **CAUTION**

Use extreme care to prevent excess lubricant from reaching the cable holding grooves. Lubricant in the cable holding grooves may cause slippage during tensioning.

CARE and HANDLING: Use extreme care in handling and storage of implant components. Cable and clasp 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 ensure 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.