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CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a licensed physician.

INFORMATION CONCERNING USE OF THE KINAMED SUPERCABLE™ GRIP AND PLATE SYSTEM

U.S. and International Patents Pending.

GENERAL INFORMATION

This document contains general information concerning the SuperCable™ Grip and Plate System.

The SuperCable™ Grip and Plate System consists of trochanteric reattachment grips, cable-plates, and cortical bone screws that are intended to be used in conjunction with 1.5mm diameter SuperCable Iso-Elastic Cerclage polymer cables. The cables pass through the grips and plates and provide fixation by attaching these devices to fractured or osteotomized bone fragments. Cortical bone screws may be used in combination with the cable-plates for additional fixation as deemed necessary by the surgeon user. The system includes a range of cable grip, cable-plate, and bone screw sizes and material options, with associated manual surgical instrumentation that provide the versatility required for treating the specific conditions listed in the INDICATIONS section below. All implants are intended for single use only and should not be reused under any circumstances.

The general principles of patient selection and sound surgical judgment apply to procedures involving these devices.

IMPLANT MATERIALS

	Titanium	Stainless Steel	Cobalt-Chrome
Grip	ISO 5832-3	ISO 5832-1	ISO 5832-4
	ASTM F-136	ASTM F-138	ISO 5832-12
	ASTM F-1295	ASTM F-139	
Cable-Plate	ISO 5832-3	ISO 5832-1	ISO 5832-4
	ASTM F-136	ASTM F-138	ISO 5832-12
	ASTM F-1295	ASTM F-139	
Screw	ISO 5832-3	ISO 5832-1	N/A
	ASTM F-136	ASTM F-138	
	ASTM F-1295	ASTM F-139	

INDICATIONS

The SuperCable™ Grip and Plate System is indicated for use where wire, cable, or band cerclage is used in combination with a trochanteric grip or bone plate. The SuperCable™ Grip and Plate System is intended to be used in conjunction with the SuperCable™ Iso-Elastic Cerclage System for reattachment of the greater trochanter following osteotomy or fracture, and for fixation of long bone fractures.

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,
- Insufficient quality or quantity of bone, which would inhibit rigid device fixation,
- Any disease affecting the support and fixation of the implant,
- 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),
- Demonstrated sensitivity to Titanium, Stainless Steel, or Cobalt-Chrome-Molybdenum or its alloys.

WARNINGS

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. Repeated bending back and forth of the plates should be avoided as this action may weaken the plate leading to plate breakage. In the absence of functional, healed bone, implant failure may occur if the bone segments are subjected to repetitive loading over time. Patients who smoke should be advised that an increased incidence of non-union has been reported in patients who smoke.

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.

Corrosion has been reported following implantation of many metallic devices. Corrosion is a byproduct of the body's natural electrochemical response to metal. Metals used in these implants are chosen for their relatively inert behavior in the body and protective surface treatments are performed on the implants where appropriate. Corrosive processes likely will shorten the useful life of the device, and could lead to an earlier than desired revision to replace the damaged components. **Stainless steel and titanium implants should never be used in combination.**

Trauma plate breakage is reported in the literature. Possible causes of breakage include, but are not limited to, over loading, fretting corrosion, 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 implants and instruments are provided non-sterile and must be cleaned and sterilized before use. Validated sterilization cycle parameters are noted in the STERILITY AND HANDLING section below.

PRECAUTIONS

Once removed from their original packaging, implants and instruments should be cleaned, stored and autoclaved in the organizer trays provided in the system to prevent contact with items of dissimilar metals. Adequate inventory of the various sizes and configurations of implants should be available in the organizer tray at the time of surgery to meet the requirements of each specific surgical case. Following use, instruments should be thoroughly cleaned prior to being replaced in the organizer tray for sterilization. Drills should be inserted only into the instruments for which they are labeled.

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.

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.

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.

PRE-OPERATIVE MANAGEMENT

1. The surgeon should consider for surgery those patients who are indicated for the use of the SuperCable™ Grip and Plate System.
2. The surgeon should not consider for surgery those patients who are contraindicated for use of the SuperCable™ Grip and Plate System.
3. The surgeon should have a complete understanding of the surgical technique and of the system design rationale, indications, contraindications, and applications.
4. The surgeon should have a complete understanding of the function and limitations of each implant and instrument. This must include working knowledge of both dynamic compression (DCP) and locking plate techniques.
5. Careful pre-operative planning should include construct strategy and verification of required inventory for the case.
6. Device components should be received and accepted only in packages that have not been damaged or tampered with. Damaged implants or instruments should not be used. Components must be carefully handled and stored in a manner that prevents scratches, damage, and corrosion.

INTRA-OPERATIVE MANAGEMENT

See SuperCable™ Grip and Plate System Surgical Technique brochure.

POST-OPERATIVE MANAGEMENT

1. The patient should have a complete understanding of and compliance with the purpose and limitations of the implant devices.
2. The surgeon should instruct the patient regarding amount and timeframe after surgery of any weight-bearing activity. 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.
3. Late postoperative complications can include:
   - o Early, or late loosening, wear, and change in position of one or more components,
   - o Trochanteric avulsion as a result of excess muscular tension, early weight bearing, or inadvertent intraoperative weakening,
   - o Trochanteric nonunion due to inadequate reattachment and/or early weight bearing,
   - o Progressive bone resorption and osteolysis.
4. The patient should be encouraged to report any unusual changes to his/her physician.

STERILITY AND HANDLING

All items in the system, including the implants, are supplied non-sterile and must be cleaned and sterilized before use. Sterilization of the instruments and implants is accomplished by autoclaving per the following recommended procedures:

Method	Cycle Type	Sterilization Temperature	Exposure Time
Steam Autoclave (Wrapped)	Pre-Vacuum	134°C to 137°C (273.2°F to 278.6°F)	3 minutes (Minimum)

Instrumentation must be thoroughly cleaned prior to autoclaving.

CLEANING and MAINTENANCE

All implants and instruments must be free of packaging material and biocontaminants prior to sterilization. Cleaning, maintenance and mechanical inspection must be performed by hospital personnel trained in the general procedures of contaminant removal.

For manual cleaning, completely submerge instruments in neutral pH endozime detergent 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. Remove instruments from the enzymatic solution and rinse thoroughly under running tap water. Thoroughly and aggressively brush and flush through cannulated areas using a water jet with the exit end submerged. For automated washing and drying following manual cleaning and rinsing, place instruments in a suitable washer basket and load in an automatic washer/drier. Cycle should be set for a Non-Caustic wash cycle for a duration of 70 minutes using a neutral pH endozime detergent. The endozime detergent should be used at a specified concentration in a 14-minute cleaning cycle.

Allow adequate time for drying. Inspect implants and instruments for dryness prior to sterilization. Compliance with equipment instructions and/or recommendations for chemical solutions is required.

CARE and HANDLING

Use extreme care in handling and storage of implant components. Implants must be handled with care. Bending, notching, or scratching the implant surfaces 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 components. 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 implant position and result in implant failure. Thorough familiarity with the surgical technique is essential to ascertain their proper working condition.

PACKAGING and LABELING

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

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.