KINAMED®
INCORPORATED

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

GENERAL REMARKS

The Kinamed Iso-Elastic Cerclage System consists of a braided cerclage cable and attached clip.

The cable is made from UHMWPE strands braided over a nylon 6/6,6 core.

The clip assembly components are made from either 316L SS (ASTM F138), Ti-4AL-6V (ASTM F136 or F1108), or CoCrMo (ASTM F1537 or F75).

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

INDICATIONS

The Cerclage Cable System is intended for:

a. Repair of long bone fractures due to trauma or reconstruction;
b. reattachment of the greater trochanter in total hip arthroplasty, surface; replacement arthroplasty, or other procedures involving trochanteric osteotomy
c. sternotomy closure; and
d. sublaminar and intrafacet wiring of the spinal column.

CONTRAINDICATIONS

The following conditions are contraindications for cerclage use:

a. Active or suspected infection, either systemic or localized, in or around the implant site.
b. Patient conditions, mental or neurological, that would tend to impact the patients ability to follow physician's instructions during the post-operative healing phase.
c. Skeletally immature patients.
d. Comprised vascularity that would inhibit adequate blood supply to the fracture or operative site.
e. Insufficient quality or quantity of bone, which would inhibit rigid device fixation.
f. Any disease affecting the support and fixation of the prosthesis.
g. 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.

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 orthopedic 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 or osteotomy 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.

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.

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 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 the use and handling of these instruments 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.

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.

INTEROPERATIVE PROCEDURES
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.

Have all operating room personnel and observers properly attired to assure sterility at the operating site.

POSTOPERATIVE 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.

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 RESTERILIZE IMPLANTS.

The cable-tensioning instrument must be sterilized prior to surgical use. Sterilize in a pre–Vac autoclave at 132º ± 1º C (270º ± 2º F) for 15 minutes, wrapped. The instrument must be thoroughly cleaned prior to autoclaving.

PACKAGING AND LABELING
See Product Label for information regarding the specific product referenced in this package insert.

Implant should be accepted only if received by the hospital or surgeon with the factory packaging and labeling intact.

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