SIGNAL MEDICAL

WARNING NOTE – Low-Profile Cable

PRECAUTIONS AND WARNINGS

For use in orthopedic surgery to provide temporary stabilization, augment the development of solid bony fusion and/or aid in the repair of bone fractures.

Device Description:
The multi-stranded cable and attached crimp is made from Cobalt Chrome (ASTM F90-92).

A. Indications

1. Trochanteric reattachment after trochanteric osteotomy following total hip arthroplasty,
2. Rewiring of osteotomized sternums,
3. Fixation of bone fractures (elbow, patella, shoulder, ankle),
4. Fixation of bone struts following total hip arthroplasty,
5. Spinal applications would include sublaminar and intraspinous process wiring for trauma applications.

B. Contraindications:

1. Uncooperative patients or patients with neurologic disorder who are incapable of following instructions,
2. Metabolic disorders that may impair bone formation,
3. Osteomalacia,
4. Distant foci of infection (which may cause hematogenous spread to the implant site),
5. Rapid joint destruction or bone resorption, and
6. Vascular insufficiency, muscular atrophy, or neuromuscular disease.

C. Warnings:

Inappropriate selection, placement, positioning, alignment and fixation of the implant components may result in abnormal stress and/or wear conditions that the implant was not designed for, thereby reducing the life of the prosthetic implant. The surgeon is to be thoroughly familiar with the implant, its components, their assembly, the instruments, and the surgical procedure prior to the surgery. Application: Tight fixation of all press-fit components intraoperatively is essential to the success of the surgery. Each component must be properly press fit into the bone stock, which demands precise surgical technique and the use of special instruments. Bone stock of adequate health must be present and identified at the time of surgery.

D. Correct Selection of Patient:

In selecting patients for total joint replacement, the following factors can be of extreme importance to the eventual success of the procedure:

1. Patient weight,
2. Patient occupation or activities,
3. Patient condition of senility, mental illness or alcoholism,
4. Certain degenerative diseases, and
5. Foreign body sensitivity.

E. Intraoperative and Postoperative Complications:

1. The correct selection of the implant is extremely important. The potential for success in total joint replacement is increased by the selection of the proper size, shape and design of the implant. No total joint replacement can be expected to withstand loads and activity levels of normal healthy bone. Total joint prostheses require careful seating and adequate bone support, and should be restricted to limited functional stress.
2. All modular components must be firmly seated to prevent disassociation. Thoroughly clean and dry all tapers prior to attachment of modular heads to avoid crevice corrosion and improper seating. Any component that is nicked, scratched or otherwise altered or damaged in any way, during insertion or at any time, can increase the possibility of fretting or crevice corrosion and should not be used.
3. Surgical debris, such as bone or tissue can cause loosening, fracture or wear of the implant, as well as damage to the bone. Complete preclosure cleaning of the implant site is critical.
4. Femoral fracture while seating the device.
5. Temporary or permanent nerve damage causing pain or numbness of the affected limb.
6. Undesirable shortening or lengthening of the limb.
7. Traumatic arthrosis of the knee from intraoperative positioning of the lower limb.
8. Cardiovascular disorder including venous thrombosis, pulmonary embolism or myocardial infarction.
9. Hematoma.
10. Increased wound healing time.
11. Infection.

F. Late Postoperative Complications:

Postoperative care is important. The patient should be instructed on the limitations of these devices and should be cautioned regarding load-bearing, range of motion, and activity level permissible. Early load-bearing should be carefully controlled. The implant cannot be expected to withstand the activity levels and loads of normal healthy bone. Excessive activity, failure to control body weight, and trauma affecting the implant have been associated with premature failure of the implant. Other complications may include:

1. Trochanteric avulsion as a result of muscular tension, early weight bearing or intraoperative weakening.
2. Trochanteric non-union, aggravated problems of the knee or ankle of the operative limb or non-operative limb.
3. Femoral fracture by excessive loading or trauma, generally in presence of weak bone stock, bone reabsorption, which may take part in diminishing fixation and loosening.

4. Perarticular calcification with or without hindering joint mobility.

G. Handling:

Use extreme care in handling and storage of implant components. Cutting, bending or scratching the surface of components can significantly 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.

H. Sterilization:

All components have been sterilized by 100% ethylene oxide gas with nitrogen in accordance with ISO 11135. Inspect packages for punctures or other damage prior to surgery. DO NOT RESTERILIZE IMPLANT. DO NOT IMPLANT A CONTAMINATED DEVICE.

I. Reuse:

A surgical implant should not be reused. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns which may lead to failure. We urge you to use only new appliances of current design.

J. Instrumentation

Specialized instruments are designed for the cable system to assist in the accurate implantation of the prosthetic components. The use of other instruments may result in inaccurate fit and sizing. Surgical instruments are subject to wear, even with normal usage. All instruments should be used only for their intended purpose. Damaged or excessively worn instruments should be replaced.

K. Possible Adverse Effects:

1. Patient sensitivity reactions to metal and foreign materials in implants following implant surgery rarely have been reported. The significance of this sensitization awaits further clinical evidence and evaluation. Evaluation of foreign material can result in histological reactions of varying degrees. The clinical significance of these reactions are uncertain, as similar changes may occur during the early healing process.
2. Peripheral neuropathies and heterotopic bone formation have been reported following joint surgery. Subclinical nerve damage occurs frequently, possibly as a result of the surgical trauma.
3. Infection can lead to implant failure.
4. Fracture of the femur can occur intraoperatively while seating the femoral component.
5. Fretting and crevice corrosion can occur at the interface between any two components.
6. The component has not been tested for compatibility within a MR (Magnetic Resonance) environment.

For More Information, Please Contact:

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