PROstep™
minimally invasive surgery

stryker

Important safety information

Indications

The MICA® Screw is indicated for fixation of bone fractures or for bone reconstruction. Examples include:
- Mono or Bi-Cortical osteotomies in the foot or hand
- Distal or Proximal metatarsal or metacarpal osteotomies
- Weil osteotomy
- Fusion of the first metatarsophalangeal joint and interphalangeal joint
- Fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)
- Akin type osteotomy
- Arthrodesis base first metatarsal cuneiform joint to reposition andstabilize metatarsus varus primus
- Calcaneus/cuboid arthrodesis
- Talar/navicular arthrodesis

Contraindications

General Surgical Contraindications:
- Infection;
- Physiologically or psychologically inadequate patient;
- Irreparable tendon system;
- Possibility for conservative treatment;
- Growing patients with open epiphyses;
- Patients with high levels of activity.

Warning

For safe and effective use of this implant system, the surgeon should be familiar with the recommended surgical procedure for this device. In every case, accepted surgical practices should be followed in post-operative care. The patient should be made aware of the limitations of the implant and that physical activity has been implicated in premature failure of similar devices. Patient sensitivity to implant materials should be considered and assessed prior to surgery. Do not modify implants.

Precautions

Following the instructions for use provided in product literature can minimize the potential for complications or adverse reactions with any implant. It is the responsibility of each surgeon using implants to consider the clinical and medical status of each patient and to be knowledgeable about all aspects of implant procedure and the potential complications that may occur. The benefits derived from implant surgery may not meet the patient's expectations or may deteriorate with time, necessitating revision surgery to replace the implant or to carry out alternative procedures. Revision surgeries with implants are common. The patient's mental status must also be considered. Willingness and/or ability to follow post-operative instructions may also impact the surgical outcome. Surgeons must balance many considerations to achieve the best result in individual patients. IF EXCESSIVE LOADING CANNOT BE PREVENTED, AN IMPLANT SHOULD NOT BE USED. The main goal of surgery with this implant is to establish bony fusion. Abnormal or excessive forces could lead to delayed union, non-union, or failure of the implant.

Abnormal force loading and subsequent wear may be caused by:
- Uncorrected instability
- Improperly sized implant
- Inadequate soft tissue support
- Implant malposition
- Excessive motion
- Uncorrected or recurrent deformity
- Patient misuse or overactivity

Proper fixation at the time of surgery is critical to the success of the procedure. Bone stock must be adequate to support the device.

Some preventative measures to consider to minimize the potential for complications:
- Follow guidelines for indications and contraindications provided below
- Identify prior pathology
- Stabilize collapse deformities
- Bone graft pre-existing cysts
- Use a properly sized implant

Avoid flawing implant surfaces or excessive bending to minimize the potential for early fatigue failure.

If complications develop, possible corrective procedures include:
- Implant removal
- Bone grafting of cysts
- Replacement of the implant

Over time, metallic implants may loosen, fracture, or cause pain after bone fracture or osteotomy is healed. Removal of metallic implants is at the surgeon's discretion, and the appropriateness of the selected procedure will be based on the surgeon's personal medical training and experience. It is imperative that adequate post-operative care and protection be provided by the surgeon. Clinical results depend on surgeon and technique, pre-operative and post-operative care, the implant, patient pathology and daily activity. It is important that surgeons obtain appropriate.

Potential complications and adverse reactions

In any surgical procedure, the potential for complications exists. The risks and complications with these implants include:
- Infection or painful, swollen or inflamed implant site
- Fracture of the implant
- Loosening or dislocation of the implant requiring revision surgery
- Bone resorption or over-production
- Allergic reaction(s) to implant material(s)
- Untoward histological responses possibly involving macrophages and/or fibroblasts
- Migration of particle wear debris possibly resulting in a bodily response
- Embolism

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at www.ifu.stryker.com for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.