Manufactured By:
Treace Medical Concepts, Inc.
100 Palmetto Park Place
Ponte Vedra, FL 32081
904-373-5940
www.treace.com

Treace Medical Concepts Hammertoe Fixation System Instructions for Use

Description

The Treace Medical Concepts (TMC) Hammertoe Fixation System is for the fixation of osteotomies and reconstruction of the lesser toes. The cannulated implant is made of PEEK (Polyetheretherketone) according to ASTM F2026 and is available in different sizes. The implants are delivered sterile packaged and for single use only.

The Implantable K-wire is made from stainless steel according to ASTM F138 and available in different sizes. The K-wire is delivered sterile packaged and for single use only.

Indications

The TMC Hammertoe Fixation System is indicated for the fixation of osteotomies and reconstruction of the lesser toes following correction procedures for hammertoe, claw toe, and mallet toe. Cannulated implants in the TMC Hammertoe Fixation System can be used with K-wires for the delivery of implants or the temporary stabilization of outlying joints (e.g. MTP Joint).

The Implantable K-wires are indicated for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants. Additionally, Implantable K-wires are indicated for the fixation of osteotomies and reconstruction of the lesser toe following correction procedures for hammertoe, claw toe, mallet toe, and metatarsophalangeal joint instability.

Contraindications

The TMC Hammertoe Fixation System does not have product specific contraindications. General surgical contraindications include:

1. Infection.
2. Patient conditions including blood supply limitations, obesity, and insufficient quantity or quality of bone.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

Warnings

For safe and effective use of this implant system, the surgeon should be familiar with the recommended surgical technique for this device (recommended surgical technique can be accessed at www.treace.com). In every case, accepted surgical practices should be followed in postoperative care. As with any implant, the patient should be made aware of the limitations of the implant and failure to comply with prescribed physical activity instructions may result in premature failure. Patient sensitivity to implant materials should be considered and assessed prior to surgery. In the case of pediatric patients, the implant system should only be used in adolescents (>12- 21 years of age), where the implant would not cross open epiphyseal plates in skeletally immature patients.

All packaging materials MUST be removed from the implant prior to implantation.

Never steam sterilize or re-sterilize plastic (PEEK) implants as it can potentially lead to device failure.

Precautions

In no circumstances should any combination with other devices of a different brand or make be used. An implant must never be reused.

Do not use if past the expiration date on the product label, if removed from the sterile field, or if the implant or packaging is damaged. Previous stresses may have created imperfections that can potentially lead to device failure. Protect implant appliances against scratching or nicking. Such stress concentration can lead to failure.

Caution: Federal law restricts this device to sale by or on the order of a physician.

Potential Adverse Events

The following are specific adverse effects, which should be understood by the surgeon and explained to the patient. These do not include all adverse effects, which can occur with surgery in general, but are important considerations specific to metallic and PEEK internal stabilization devices. General surgical risks should be explained to the patient prior to surgery:

- Infection or adverse reactions for a foreign body;
- Pain, discomfort, or abnormal sensations due to the presence of the implant;
- Loosening, bending, cracking, or fracture of the components or loss of fixation of bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures; loss of anatomic position with nonunion or malunion with rotation or angulation;
- Migration of the implant, loosening of the implant;
- Delayed correction in alignment;
- Decrease in bone density due to stress shielding;
- Bursitis.

Revision Surgery or Removal

PEEK and metallic implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after a fracture is healed. If any of these complications occur, the surgeon must make the final decision on implant removal. Should the decision be made to remove the implants, each implant can be removed by accessing the implant with general instrumentation. For the PEEK implant, if tissue or bone growth prevents access, a powered saw may be used to cut through the PEEK implant only. The implant can then be removed by generally available surgical instrumentation.

MR Safety Information

The devices described in these instructions for use have not been evaluated for safety in the MR environment. They have not been tested for heating or unwanted movement in the MR environment. The safety of these devices in the MR environment is unknown. Performing an MR exam on a person who has these medical devices may result in injury or device malfunction.

Packaging, Cleaning, Sterilization

This product has been sterilized via gamma irradiation and should be considered sterile unless the inner package has been opened or damaged. If the inner package integrity has been compromised, contact the manufacturer for instructions. Remove from package, using aseptic OR technique, only after the correct size has been determined and the operative site has been prepared for final implantation. Always handle the product with powder-free gloves, and avoid contact with hard objects that may damage the product.

All components of this product are for single use only. An implant should never be re-sterilized. Devices labeled for single-use only should never be reused. Reuse of these devices may potentially result in serious patient harm. Examples of hazards related to the reuse of these devices include, but are not limited to: significant degradation in device performance, cross-infection, and contamination.

Storage

All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.

For product experience feedback, call 904-373-5940 or email pe@treace.net.