

Treace Medical Concepts Plating System Instructions for Use

Description

The Treace Medical Concepts (TMC) Plating System includes straight, L-shaped, H-shaped, and anatomically curved plates and 2.5 mm, 2.7 mm, and 3.0 mm diameter screws in lengths ranging from 10-32 mm. The plates and screws are composed of titanium alloy conforming to ASTM F136.

Indications

The TMC Plating System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the feet. The system can be used in both adult and pediatric patients aged >12 years. In the foot, the system can be used for the following specific examples:

- First metatarsal osteotomies for hallux valgus correction such as:
 - Opening base wedge osteotomy
 - Closing base wedge osteotomy
 - Crescentic osteotomy
 - Proximal Chevron osteotomy
 - Distal Chevron osteotomy (Austin)
- Arthrodesis of the tarsometatarsal (TMT) joints or the 1st metatarsophalangeal (MTP) joint for the treatment of deformity (e.g., hallux valgus, hallux rigidus, metatarsus adductus) and / or arthritis
- First metatarsal fracture fixation
- Flatfoot Osteotomies
 - Lateral Column Lengthening (Evans Osteotomy)
 - Plantar Flexion Opening Wedge Osteotomy of the Medial Cuneiform (Cotton Osteotomy)
- Mid / Flatfoot Fusions
 - LisFranc Arthrodesis and/or Stabilization
 - Intercuneiform Fusions
 - Navicular-Cuneiform (NC) Fusion
 - Talo-Navicular (TN) Fusion
 - Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusion

Contraindications

The TMC Plating 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. 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. 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.

Precautions

All devices in this range must be implanted using specific ancillaries designed for the purpose. In no circumstances should any combination with other devices of a different brand or make be used. An implant must never be reused. 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.

Do NOT permanently implant K-wires through the holes of the plate as they may back

out and cause tissue damage. Use of the K-wires allows you to provisionally secure the plates to the anatomy. Do NOT permanently implant instruments including drill guides, plate trials, and all other instruments.

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 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

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 implant, the screws and plates may be removed by using the appropriate screwdriver. If there is tissue growth within the head of the screw that prevents insertion of the screwdriver, the tissue may be removed with a generally available surgical instrument.

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 this medical device 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 after contact with body tissues or fluids.

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.

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

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

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

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