

## 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 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. 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)
- First metatarsal fracture fixation
- Arthrodesis of the first metatarsal cuneiform joint (Lapidus Fusion)
- 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
  - 1st (Lapidus), 2nd, 3rd, 4th, and 5th Tarsometatarsal (TMT) Fusions
  - Intercuneiform Fusions
  - Navicular-Cuneiform (NC) Fusion
  - Talo-Navicular (TN) Fusion
  - Calcaneo-Cuboid (CC) Fusion
- Medial Column Fusion
- Arthrodesis of the first metatarsophalangeal joint (MTP)

### 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](http://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.

### 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. Orthopaedic instrumentation does not have an indefinite functional life. All reusable

instruments are subjected to repeated stresses related to bone contact, impaction, routine cleaning and sterilization processes. Instruments should be carefully inspected before each use to ensure that they are fully functional. Scratches or dents can result in breakage. Dullness of cutting edges can result in poor functionality. Damaged instruments should be replaced to prevent potential patient injury such as metal fragments into the surgical site. Care should be taken to remove any debris, tissue or bone fragments that may collect on the instrument. 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.

### 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.

### Magnetic Resonance Environments

The devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. The devices described in this package insert have not been tested for heating or migration in the MR environment.

### 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.

For product experience feedback, call 904-373-5940 or email [cs@treace.net](mailto:cs@treace.net).