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

Treace Medical Concepts Compression Implant System Instructions for Use

Description

The Treace Medical Concepts (TMC) Compression Implant System consists of implants composed of titanium alloy (conforming to ASTM F136) and related instrumentation for implantation. The system includes locking screws and compression implants offered in multiple combinations of bridge lengths, leg lengths, and cross sections to accommodate various anatomies.

Indications

The system is intended to be used for fracture fixation, osteotomy fixation, and joint arthrodesis of the foot and ankle.

Contraindications

The 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 implants as they may back out and cause tissue damage. Use of the K-wires allows you to provisionally secure the implants to the anatomy. Do NOT permanently implant 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 implants can be removed by using a screwdriver for unscrewing the screws, if applicable, and reattaching the implant inserter instrument and/or using general orthopedic instrumentation to remove the implant. If there is tissue growth within the implant that prevents removal, 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.

09-00005L Rev. D – 11/24