Manufactured By:
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Treace Medical Concepts Compression Screw System Instructions for Use

Description

The Treace Medical Concepts (TMC) Compression Screw System includes headed and headless cannulated screws, lengths 10mm-100mm (2mm increments up to 50mm, then 5mm increments to 100mm) and 23mm. The diameters are 2.0mm to 7.5mm (in 0.5mm increments) and 3.3mm. The screws are composed of titanium alloy conforming to ASTM F136.

Indications

The TMC Compression Screw System is intended for use for adult and pediatric patients aged >12 years, as indicated for small or long bones requiring fixation of fractures, fracture repair, revision procedures, joint fusions (arthrodesis), bone reconstructions, osteotomy, ligament fixation, and pseudoarthrosis (non-unions) of bones, including scaphoid and other carpal bones, metacarpals, tarsals, metatarsals, phalanges, patella, ulnar styloid, capitellum, radial head and radial styloid.

In the foot, the following specific examples are indicated with screws appropriate for the size of the device:

- mono or bicortical osteotomies
- distal or proximal metatarsal osteotomies
- weil osteotomy
- fusion of the metatarsalphalangeal joint
- fixation of osteotomies for Hallux Valgus treatment (such as Scarf, Chevron, etc.)
- Akin type osteotomy
- talonavicular fusions
- cuboid fusions

Not for spinal use.

Contraindications

The TMC Compression Screw 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.

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 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 screw may be removed by using the appropriately sized Hexalobular 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.

Compatibility with Magnetic Resonance Environments

The devices described in these instructions for use have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of these devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 pe@treace.net.

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