

Treace Medical Concepts Screw Fixation System Instructions for Use

Description

The Treace Medical Concepts (TMC) Screw Fixation System includes headed and headless, cannulated screws and non-cannulated lengths 8mm-150mm and diameters from 2.0mm to 7.5mm. The screws are composed of titanium alloy conforming to ASTM F136.

Indications

The TMC Screw Fixation System is intended for primary and revision fracture fixation and repair, joint fusions (arthrodesis), bone reconstructions, osteotomies, pseudoarthroses (non-unions), and ligament fixation. The System is indicated for use in adult and pediatric patients > 12 years of age at the following anatomical sites:

- Upper extremity: glenoid, humerus, ulna, radius, and hand
- Lower extremity: tibia, fibula, patella, ankle, and foot. Indicated procedures include:
 - o Fusions (e.g., talocalcaneal, talonavicular, naviculocuneiform, calcanealcuboid, tarsometatarsal, metatarsophalangeal, and interphalangeal)
 - o Mono or bi-cortical osteotomies of the tarsals, metatarsals, and phalanges (e.g., Scarf, Chevron, Akin, Weil, and Transverse osteotomies for hallux valgus, tailor's bunion, metatarsus adductus, flatfoot, and hammertoe deformities).

Contraindications

The TMC Screw 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. 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 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.

MRI 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, for pouches or trays, the inner package has been opened or damaged, or for sterile tubes if the tamper evident label is ripped on either side. If the inner package integrity, in the case of pouches or trays, or the tamper-evident label, in the case of tubes, 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.

Symbol	Title	Standard Designation	Description of Symbol
	<i>Manufacturer</i>	ISO 15223-1 5.1.1	<i>Indicates the medical device manufacturer</i>
	<i>Use-by date</i>	ISO 15223-1 5.1.4	<i>Indicates the date after which the medical device is not to be used</i>
	<i>Batch code</i>	ISO 15223-1 5.1.5	<i>Indicates the manufacturer's batch code so that the batch or lot can be identified</i>
	<i>Catalogue number</i>	ISO 15223-1 5.1.6	<i>Indicates the manufacturer's Catalogue number so that the medical device can be identified</i>
	<i>Sterilized using irradiation</i>	ISO 15223-1 5.2.4	<i>Indicates a medical device that has been sterilized using irradiation</i>
	<i>Non-sterile</i>	ISO 15223-1 5.2.7	<i>Indicates a medical device that has not been subjected to a sterilization process</i>
	<i>Do not use if package is damaged and consult instructions for use</i>	ISO 15223-1 5.2.8	<i>Indicates that a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information</i>
	<i>Do not re-use</i>	ISO 15223-1 5.4.2	<i>Indicates a medical device that is intended for one single use only</i>
	<i>Consult instructions for use or consult electronic instructions for use</i>	ISO 15223-1 5.4.3	<i>Indicates the need for the user to consult the instructions for use</i>
	<i>Caution</i>	ISO 15223-1 5.4.4	<i>Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences</i>
	<i>Prescription Use Only</i>	21 CFR Part 801, Sec. 801.109	<i>Caution: Federal law restricts this device to sale by or on the order of a physician</i>
 Do not re-sterilize	<i>Do not re-sterilize</i>	ISO 15223-1 5.2.1	<i>Indications that a medical device is not to be resterilized</i>