

# Instructions For Use

## TCP - Total Compression Plate System

### Package Insert / Important Medical Information



#### DESCRIPTION

The TC Plating System is comprised of a variety of titanium plates with shapes and sizes designed for internal fixation of small bone fragments. Most of the plates are scalloped in shape to allow easier bending to fit the contour of the bone. There are also non-scalloped plates to provide greater strength. The plates include straight, right, and left configurations.

#### INDICATIONS

The TC Plating System is intended for essentially non-load bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, pelvis and craniomaxillofacial skeleton.

#### CONTRAINDICATIONS

Orthopaedic plates and screws are contraindicated in:

- Active Infection;
- Conditions which tend to retard healing such as blood supply limitations previous infections;
- insufficient quantity or quality of bone to permit stabilization of the osteotomy;
- Lack of musculo-cutaneous cover;
- Muscular deficit, neurological deficiency or behavioral disorders which could submit the osteosynthesis to abnormal mechanical strains;
- Cases with malignant primary or metastatic; tumors which preclude adequate bone support or screw fixations;
- conditions that restrict the patient's ability or willingness to follow postoperative instructions during the healing process;
- foreign body sensitivity;

#### PRECAUTIONS

All devices in this range must be implanted using specific OrthoPro ancillaries designed for the purpose. In no circumstances should any combination with other devices of a different brand 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 re-usable 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. Many instruments are intended for use with a specific implant system. It is essential that the surgeon and operating theatre staff are fully conversant with the appropriate surgical technique for the instruments and associated implant, if any. Exercise care when bending the plates to avoid weakening or fracture of the plates. 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.

#### WARNINGS

For safe and effective use of this implant system, the surgeon should be familiar with the recommended surgical procedure for this device. 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. Do not modify implants. Do not bend or cut them.

#### IMPLANT MATERIALS

The TCP implants are manufactured from titanium alloy (Ti -6Al-4V ELI, ASTM F136).

#### ADVERSE EFFECTS

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.

#### PACKAGING AND STERILITY

The system is provided non-sterile and should be steam sterilized at the surgical facility before use.

The system must be cleaned prior to sterilization. Clean and inspect all instruments within the system to ensure they are suitable for use. Cracked or bent instruments should be replaced.

The system must be steam sterilized using the following process parameters:

Sterilizer Type:	Prevacuum
Preconditioning Pulses:	3
Minimum Temperature:	132°C ( 270°F)
Full Cycle Time:	4 Minutes
Minimum Dry Time:	55 Minutes
Sample Configuration:	Wrapped tray with a towel placed between tray and wrap

Sterilizer Type:	Gravity
Minimum Temperature:	132°C ( 270°F)
Full Cycle Time:	18 Minutes
Minimum Dry Time:	45 Minutes
Sample Configuration:	Wrapped tray with a towel placed between tray and wrap

The use of flash sterilization is not recommended.

Remove all packaging materials prior to sterilization. Only implants and instruments should be used in surgery. Immediately clean and re-sterilize all items removed from the surgical field before handling. Surgical implants shall not be re-used. Any implant once used shall be discarded. Even though it may appear undamaged, it may have small defects or internal stress patterns which may lead to failure.

#### CAUTION:

Federal Law (United States) restricts this device to sale, distribution, and/or use by or on the order of a physician.

#### FURTHER INFORMATION

For further information, please contact:  
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Please contact company for product inquiries and surgical techniques, or to report any adverse experience.