



## TOTAL COMPRESSION PLATE (TCP) SYSTEMS

152151-1

**The following languages are included in this packet:**

English (en)

For additional languages, visit our website [www.wmt.com](http://www.wmt.com). Then click on the **Prescribing Information** option.

**For additional information and translations please contact the manufacturer or local distributor.**



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**Rx ONLY**

November 2014  
Printed in U.S.A.



*Attention Operating Surgeon*  
**IMPORTANT MEDICAL INFORMATION**  
**TOTAL COMPRESSION PLATE (TCP) SYSTEMS**  
(152151-1)








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## DEFINITIONS

Symbols and abbreviations may be used on the package label. The following table provides the definition of these symbols and abbreviations.

Table 1. Definitions of Symbols and Abbreviations

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Consult operating instructions
	Use by
	Temperature limitation

	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
	Authorized EC Representative in the European Community
	Non-sterile
	For prescription use only
	Do not use if packaging is ripped or damaged.
<b>Abbreviation</b>	<b>Material</b>
Ti6Al4V	Titanium Alloy

## **I. SPECIFIC PRODUCT INFORMATION**

### **A. SMALL BONE / MIDFOOT SYSTEM**

#### **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 and pelvis.

Specific examples of use in the foot include:

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

First metatarsal osteotomies for hallux valgus correction including:

- 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 metatarsalcuneiform joint (Lapidus Fusion)

Arthrodesis of the first metatarsophalangeal joint (MTP) including:

- Primary MTP Fusion due to hallux rigidus and/or hallux valgus
- Revision MTP Fusion
- Revision of failed first MTP Arthroplasty implant

## **B. ANKLE TRAUMA SYSTEM**

### **DESCRIPTION**

The Ankle Trauma System is comprised of a variety of titanium plates with shapes and sizes designed for internal fixation of long bones and bone fragments. The plates include straight, right, and left configurations. The system also includes bone screws. Manual surgical instruments are supplied with the system to facilitate implantation.

### **INDICATIONS**

The Ankle Trauma System is intended for fixation of fractures, osteotomies, and non-unions of the clavicle, scapula, olecranon, humerus, radius, ulna, pelvis, distal tibia, and fibula, particularly

in osteopenic bone. The Ankle Trauma system is intended for fixation of complex intra- and extra-articular fractures and osteotomies of the distal tibia and other small bones as a part of the system.

## **II. GENERAL PRODUCT INFORMATION**

### **A. CONTRAINDICATIONS**

No product specific contraindications. General surgical contraindications include:

- 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.

### **B. PRECAUTIONS**

All devices in this range must be implanted using specific WMT 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.

#### **C. 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.

#### **D. 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.

#### E. IMPLANT MATERIALS

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

#### F. PACKAGING AND STERILITY

The system is provided non-sterile and should be steam sterilized at the surgical facility before use. The system must be steam sterilized using the following process parameters:

Steam Sterilization		
Sterilizer Type	Parameter	Minimum Set Point
Prevacuum	Temperature	132°C ( 270°F )
	Full Cycle Time	4 minutes
	Dry Time	30 minutes
Wrapped in two layers of 1-ply polypropylene wrap (Kimguard KC600-510(k) K082554) using sequential envelope folding techniques		

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.

#### **G. INSTRUMENT CLEANING**

The instruments must be cleaned prior to sterilization. Carefully inspect all instruments within the system to ensure they are suitable for use and have not been damaged (i.e. cracks, bends, twisting, dull cutting surfaces, etc.). Devices must be manually cleaned before being processed in the Automatic Washer/Disinfector.

##### Preparation

It is recommended that devices should be reprocessed as soon as is reasonably practical following use. Soak and/or rinse heavily soiled devices prior to cleaning to loosen any dried soils or debris. Lumens/ cannula should be cleared of soil or debris. This can be accomplished through using appropriate sized soft-bristle brushes and inserting the brushes into the cannula using a twisting motion.

##### Manual Pre-clean

Perform the manual pre-clean using the following steps.

1. Rinse soiled devices under cold running tap water for one minute or until the visible soil is removed. Use a soft-bristle brush or lumen brush to assist in the removal of soil and debris.
2. Fully immerse the instruments in a neutral ph (7.0) enzymatic cleaner made per manufacturer's recommendations using lukewarm tap water.
3. Manually clean (scrub) the device using a soft-bristle brush removing all visible soil and debris. Pay particular attention to any threads, pivots, cannula, recesses, blind holes or difficult to reach

areas. Be sure to thoroughly clean cannulated products using an appropriate size brush. The brush should be repeatedly run through the entire length of the cannula using a twisting motion. Flush the cannula with water until the rinse stream is clear.

4. Rinse the devices thoroughly for 1 minute at room temperature (20°-25°C) water. Water must be purified (deionized (DI), distilled, etc.). Use a syringe, water jet, or pipette to flush cannula, blind holes, and channels.
5. If soil or debris are still visible repeat steps 1-4 until all visible soil or debris have been removed from the device.
6. Dry the device thoroughly using a clean, soft, lint-free cloth or compressed air (30-40psi).

#### Automatic Processing Parameters

After the manual pre-clean has been performed the parts will be processed in the automated cleaner (washer/disinfector) using the following steps.

1. Place devices into an automatic washer/disinfector and process using the following parameters.
2. Pre Wash; Cold Tap Water; 2 minutes
3. Enzyme Wash; Hot Tap Water; 1 minute
4. Detergent Wash; Hot Tap Water (64°C -66°C): 2 minutes
5. Rinse; Hot Tap Water; 15 seconds
6. Pure Water Rinse (64°C -66°C); Heated, 10 seconds
7. Hot Air Dry; (98.8°C); 7-30 minutes

## H. CAUTION

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

### Recommendations Regarding Device Fragments

- Use medical devices in accordance with their labeled indications and Wright Medical Technology's instructions for use, especially during insertion and removal.
- Inspect devices prior to use for damage during shipment or storage or any out-of-box defects that might increase the likelihood of fragmentation during a procedure.
- Inspect devices immediately upon removal from the patient for any signs of breakage or fragmentation.
- If the device is damaged, retain it to assist with Wright Medical Technology's analysis of the event.
- Carefully consider and discuss with the patient (if possible) the risks and benefits of retrieving vs. leaving the fragment in the patient.
- Advise the patient of the nature and safety of unretrieved device fragments including the following information:
  - a. The material composition of the fragment (if known);
  - b. The size of the fragment (if known);
  - c. The location of the fragment;
  - d. The potential mechanisms for injury, e.g., migration, infection;
  - e. Procedures or treatments that should be avoided such as MRI exams in the case of metallic fragments. This may help to reduce the possibility of a serious injury from the fragment.

**Concerning Magnetic Resonance Environments**

There are inherent risks associated with the use of metallic implants in the MR environment; including component migration, heat induction, and signal interference or distortion near the component(s). Heat induction of metallic implants is a risk related to component geometry and material, as well as the MR power, duration, and pulse sequence. Since MR equipment is not standardized, the severity and likelihood of occurrence are unknown for these implants.

This system has not been evaluated for safety and compatibility in the MR environment. This system has not been tested for heating or migration in the MR environment. Since these devices have not been tested, Wright cannot make a recommendation for the use of MRIs with these implants, neither for safety considerations nor imaging accuracy.

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