1) Small Bone/Midfoot
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 non-scarpered in shape to allow easier bending to fit the contour of the bone. There are also non-scarpled 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.

2) Ankle Trauma System
DESCRIPTION
The OrthoPro 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 OrthoPro 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 osteoporotic bone. The OrthoPro 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.

CONTRAINDICATIONS
Orthopaedic plates and screws are contraindicated in:
-Active infection;
-Conditions which tend to retard healing such as blood supply limitations previous infections;
-Sufficiently small 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 fixation;
-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 which 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.

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.

IMPLANT MATERIALS
The OrthoPro Total Compression Plate System implants are manufactured from titanium alloy (Ti-6Al-4V ELI, ASTM F136).

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.

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

Sterilizer Type:  Pre-Vacuum
Preconditioning Pulses:  4
Minimum Temperature:  132°C (270°F)
Full Cycle Time:  4 Minutes
Minimum Dry Time:  30 Minutes
Sample Configuration:  Wrapped in two layers of 1-ply polypropylene wrap

The use of flash sterilization is not recommended.

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 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. Pay particular attention to any threads, pivots, cannula, recesses, blind holes or edges 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.
2. Rinse the devices thoroughly for 1 minute with 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.
3. If soil or debris are still visible repeat steps 1-4 until all visible soil or debris have been removed from the device.
4. 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

CAUTION:
Federal Law (United States) restricts this device to sale, distribution, and/or use by or on the order of a physician. The OrthoPro Total Compression Plate Systems have not been evaluated for safety and compatibility in the MR environment. The OrthoPro Total Compression Plate Systems have not been tested for heating or migration in the MR environment.

FURTHER INFORMATION
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