
CheckMate™ Metatarsophalangeal Arthrodesis System

DESCRIPTION

The CheckMate™ Metatarsophalangeal (MTP) Arthrodesis System consists of anatomically contoured bone plates, and screws (Locking, Non-Locking and Interfragmentary), which are intended to be used for surgical fusion (arthrodesis) of the 1st MTP joint.

The CheckMate™ MTP surgical instruments are designed to be used in the sizing, location, and delivery of the CheckMate™ MTP bone plate and bone screw fixation components. These instruments (except the guide pin, drill pin and tack pins i.e. the Pin Kit) are designed for repeated use, with proper care and handling.

MATERIALS

Bone Plates:	Titanium Alloy (Ti-6Al-4V)-Anodized Type II
Locking Screws:	Titanium Alloy (Ti-6Al-4V)-Anodized Medium Blue
Non-Locking Screws:	Titanium Alloy (Ti-6Al-4V)-Anodized Gold
Interfragmentary Screws:	Titanium Alloy (Ti-6Al-4V)-Anodized Magenta
Surgical Instruments:	Medical Grade Titanium, Stainless Steel and High Temperature Plastics

INDICATIONS FOR USE

The CheckMate™ Metatarsophalangeal (MTP) Arthrodesis System is intended for use in stabilization and fixation of the 1st MTP joint in the foot for fusion, osteotomy, nonunion, malunion or revision surgery.

PATIENT POPULATION

Patient Selection Factors to be Considered Include:

- Patient's need to obtain pain relief and improve function (daily activities) is significant
- Failure of previous less joint motion compromising treatment options
- Degree of osteopenic or osteoporotic bone
- Patient's age indicative of skeletal maturity
- Patient's overall well-being, including the ability and willingness to follow post-operative treatment regimen

CONTRAINDICATIONS

Absolute Contraindications with the use of CheckMate™ MTP Arthrodesis System Include:

- Previous or current infection at or near the implantation site
- Pre-existing conditions such as limited blood supply that may significantly affect the healing response
- Patients having malignant primary or metastatic tumors that may preclude adequate bone support or screw fixation
- Patients with known allergies or hypersensitivity to titanium alloys typically used in prosthetic devices

Relative Contraindications with the use of CheckMate™ MTP Arthrodesis System Include:

- Conditions that restrict the ability or willingness of the patient to follow pre and post-operative instructions
- Poor bone quality or quantity that may lead to inadequate stabilization/fusion of the joint complex
- Metabolic disorders that may impair the formation or healing of bone
- Infections at remote sites which may spread to the implant site
- Rapid joint destruction or bone resorption visible on roentgenogram

WARNINGS AND PRECAUTIONS

- Preoperative and operative procedures, including knowledge of surgical technique, good reduction, proper selection and placement of the CheckMate™ MTP implants are important considerations in the successful utilization of the CheckMate™ MTP Arthrodesis System.
- For success with the use of the CheckMate™ MTP Arthrodesis System, preoperative patient evaluation is extremely important. Patient's weight, occupation, activity level, mental condition, foreign body sensitivity and any degenerative diseases are important factors to consider. These conditions must be evaluated as a part of the preoperative planning.
- The CheckMate™ MTP Bone Plates and Screws CANNOT be expected to withstand any range of motion. These implants are intended to be used as a guide to normal healing, and not to replace normal body structure. Loading forces across the fusion site should be avoided in the sagittal plane until bony union is achieved.
- Delayed union or nonunion in the presence of motion or forces across the fusion site may lead to implant breakage due to metal fatigue. All surgical metallic implants are subjected to repeated stresses that can result in metal fatigue.
- It is very important to maintain the implant site in an immobilized state until bony union is confirmed via clinical or radiographic examination. Failure to do so will result in excessive and repeated stresses being placed on implant components that are transmitted by the body to any temporary internal fixation device. This can eventually lead to bending or breaking of the device due to normal metal fatigue.
- Postoperative care is extremely important. The surgeon must warn the patient against noncompliance with postoperative instructions, which could lead to implant bending or breakage requiring a revision surgery and/or implant removal.
- Unless otherwise noted, the patient should employ adequate external support and restrict physical activities that may lead to stresses being placed on the implant components or allow motion at the fusion site and thus lead to delayed healing. An active, debilitated or demented patient who cannot properly utilize weight support devices may be at higher risk during postoperative rehabilitation.
- Accepted practices in postoperative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to postoperative instructions and activity restrictions. Excessive activity, impact, and weight gain have been implicated in the reduction of the benefit and service life of prosthetic devices.
- Correct selection of the implant components is extremely important. It leads to potential for success in joint fusion and/or fracture fixation. The patient's anatomy and indication will determine the size of the bone screws to be used. The size and shape of human bones (specifically of the foot for this implant system) presents limitations on the size and strength of the implant components.
- Correct implant handling is extremely important for successful outcomes. The design of the CheckMate™ MTP bone plate allows for some degree of intraoperative contouring. The bone plate is pre-designed to include a dorsiflexion angle of 8 degrees. Based on the individual patient's anatomy the surgeon may use the provided benders to increase the dorsiflexion angle to a maximum value of 20 degrees. Note: Implant components should not be reverse bent, notched or scratched. All of these operations can produce defects in the surface finish and cause internal stress concentrations, which may become the focal point for eventual failure of the implant system.
- The pre-assembled nubbins (on the bone plates) should be removed and discarded after their intended use. These are temporary guidance devices that are not intended for implantation. Failure to remove nubbins will lead to improper fixation and hence device failure, and compromise patient safety.
- Care needs to be taken while using the guide pin and temporary tack pins. These pins may bend if handled incorrectly, leading to incorrect drill axis and thus improper bone plate and screw placement. Additionally, care should be taken while inserting these pins to avoid either too shallow or too deep placement. Insertion depth of guide pin depends on individual patients and the surgeon should take special care to avoid insertion of guide pins into adjacent bone and/or soft tissues.
- No other metallic or non metallic (implantable or not) devices are to be used in conjunction with the CheckMate™ MTP implant system at the implant site (i.e. the 1st MTP joint). Doing so may compromise implant performance and patient safety.
- No CheckMate™ MTP implant component must be reused. Any of the CheckMate™ MTP bone plates or bone screws once used, should be discarded. Although it may appear undamaged, the used implant component may have small defects and internal stress patterns that may lead to failure. The CheckMate™ MTP implant components are Single Use devices that have not been designed to undergo or withstand any form of alterations, such as disassembly, cleaning or re-sterilization, after single patient use. Reuse can eventually compromise implant performance and patient safety.

- Implant removal is at the sole discretion of the surgeon. Whenever possible and practical for the individual patient, the CheckMate™ MTP implants (bone plates and bone screws) should be removed once their service as an aid to the healing process is accomplished, particularly in younger and more active patients. Great care must be taken while removing the implant components.
- Use of instruments from other systems may result in improper implant selection, placement and fixation, which could result in implant failure, poor clinical outcome or compromise patient safety.
- The CheckMate™ MTP instrument set should be inspected by surgeon or surgical staff prior to use for any signs of wear or damage. Any discrepancies, damages or other issues with the use of these instruments should be reported and brought to the notice of the manufacturer.
- The CheckMate™ MTP Arthrodesis System (bone plates and bone screws) has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating or migration in the MR environment.

POSSIBLE ADVERSE EFFECTS

- Loosening, bending, cracking or fracture of the bone plate and bone screws attributable to malunion, nonunion or osteoporosis.
- Loss of anatomic position with malunion or nonunion with rotation or angulation.
- Infection, both deep or superficial, or allergic reaction.
- Material sensitivity reactions. Implantation of foreign material in tissues can result in histological reactions. Particulate wear debris and mild tissue discoloration from metallic components have been noted in other prosthetic devices constructed from similar materials. Some types of wear debris have been associated with osteolysis and implant loosening.
- Fretting or crevice corrosion can occur at the interface of bone plate and bone screws.
- Fatigue fracture of the implants as a result of bone resorption around the implant components.
- Intraoperative or postoperative bone fracture.
- Postoperative pain or incomplete resolution of preoperative symptoms.

STERILITY