



ToeMATE® Hammertoe Correction System

Description

The ToeMATE® Hammertoe Correction System consists of two intramedullary bone screws, a taper lock pin and a set of instruments used for implant site preparation and delivery. The implants are offered in three size options, x-small, small and large. The taper lock pin provides a press fit connection between the two screws with light contact pressure and is available in straight and angled configurations. The implant components are manufactured using implant grade titanium alloy and cobalt-chrome alloy.

Materials

Intramedullary Bone Screws: Titanium Alloy (Ti-6Al-4V)
Taper Lock Pin: Cobalt-Chrome Alloy (Co-Cr)

Indications for Use

Indicated for small bone fusion, fractures and inter-digital fusion of the fingers, toes and small bones.

Patient Population

Patient Selection Factors to be Considered Include:

- Failure of previous conservative treatment options in correcting deformity and achieving pain relief.
- Adequacy of bone stock to support implant components.
- Patient's age indicative of skeletal maturity.
- Functionality and/or stability of patient's musculotendinous system.
- Patient's overall well-being, including the ability and willingness to follow pre and post-operative treatment regimen.

Contraindications

Absolute Contraindications with the Use of the ToeMATE® Hammertoe Correction 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 implant grade titanium alloy and/or cobalt-chrome alloy typically used in prosthetic devices.

Relative Contraindications with the Use of ToeMATE® Hammertoe Correction System Include:

- 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

- To achieve desired outcomes with the ToeMATE® Hammertoe Correction System, pre-operative 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. Based on these the surgeon must decide whether the implant components are viable for the individual patient.
- Pre-operative and operative procedures, including knowledge of surgical technique, proper selection and placement of implant components are important considerations in the successful utilization of this system.
- The potential for success in joint fusion and stabilization is increased by proper implant size selection. The individual patient's anatomy will determine whether the ToeMATE® Hammertoe implant components can be used. The size and shape of human bones presents limitations on the size and strength of the implant components.
- These implant components are manufactured from metal, and CANNOT be expected to withstand the range of motion, activity level and loads experienced by normal, healthy bone. These implants are intended to be used as a guide to normal healing, and not to replace normal body structure.
- 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, which can lead to bending or breaking of the implants due to normal metal fatigue.

- The presence of motion or forces across the fusion site in cases of delayed union or nonunion may lead to implant bending or breakage.
- All surgical implants are subjected to repeated stresses that can result in failure. The use of an implant should be avoided if excessive loading cannot be prevented at or near the implant site.
- Post-operative care is extremely important. The surgeon must warn the patient against noncompliance with post-operative 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 post-operative rehabilitation.
- Accepted practices in post-operative care should be used. The patient is to be instructed and monitored to ensure a reasonable degree of compliance to post-operative 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 implant handling is extremely important for successful outcomes. Implant components should not be bent, 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.
- No other metallic or non metallic implantable devices are to be used in conjunction with the ToeMATE[®] Hammertoe Correction System at the implant site. Doing so may compromise implant performance and patient safety.
- This system comprises a dedicated set of instruments intended for implant site preparation and delivery. Use of instruments from other manufacturer's systems will lead to improper implantation, damage the implant components and thus compromise patient safety.

- No implant component must be reused. All 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. Great care must be taken while removing the implant components since it carries a risk of damage to the neurovascular structures. Adequate and appropriate postoperative care should be employed to stabilize the joint and avoid fracture or refracture.
- The implants and instruments 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 packaging, labeling or implant/instrument components should be reported and brought to the notice of the manufacturer. Do not use damaged or malfunctioning implants and instruments.

MR Safety Information

- The ToeMATE[®] Hammertoe Correction System implant components have not been evaluated for safety and compatibility in the MR environment. These have not been tested for heating, migration or image artifact in the MR environment. The safety of the ToeMATE[®] Hammertoe Correction System implant components in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Possible Adverse Effects and Complications

- Loosening, bending, cracking or fracture of the implant components 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.
- Embolism

- Tissue reactions such as macrophage and foreign body reaction at or near implant site.
- 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.
- Post-operative pain or incomplete resolution of pre-operative symptoms.

Sterility

The ToeMATE® Hammertoe Correction System components, i.e. implants and instruments, are packaged and provided STERILE. Sterilization is achieved by exposure to gamma irradiation. Do not resterilize any components. Do not use if packaging is opened or damaged. Do not use if beyond expiration date. For Single Use Only.

Caution

Federal Law (USA) restricts this device to sale by or on the order of a physician.

Surgical Procedure

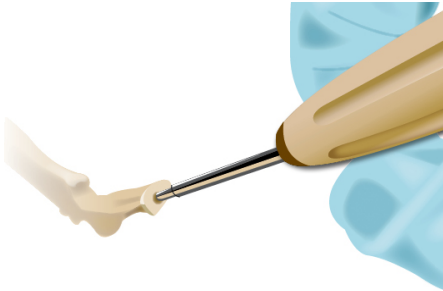
A Surgical Technique Guide that outlines the procedure with the use of the **ToeMATE® Hammertoe Correction System** is available. It is the surgeon's responsibility to become familiar with the procedure and obtain necessary training prior to performing implantation using this system. All surgeons are required to evaluate the appropriateness of the described surgical technique based on personal experience and medical training.

The basic outline of the procedure is as follows:

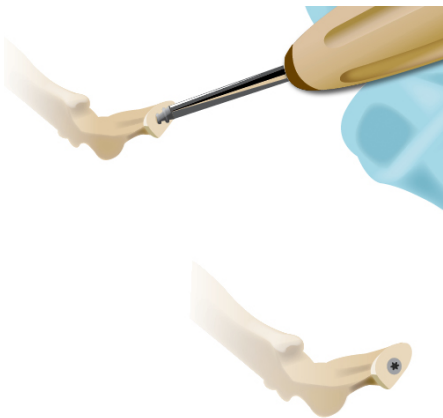
1. Resect articular surfaces of the proximal interphalangeal joint (PIPJ) i.e. proximal phalanx head and middle phalanx base, perpendicular to longitudinal axis of those bones.
Note: If plantar flexion is desired, resect one of the two surfaces at 10° and use the angled taper lock pin.



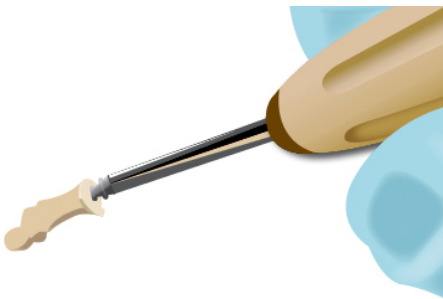
2. Create pilot holes in the proximal and middle phalangeal bones by driving the **Hand Drill** in the central canal, along the long axis of the bones. If using the x-small implant, use the provided **Guide Pin** to create the pilot hole.



3. Insert **Proximal Screw** (Purple) using the **Screw Driver** provided. Insertion is complete when the drive end of the implant is flush with the resected bone surface. Note: Select Large, Small or X-Small implant size based on the size of the patient's toes. The X-Ray template can be used to determine the appropriate size.



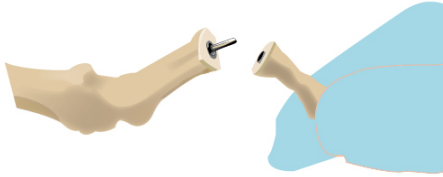
4. Similarly, insert the **Distal Screw (Gold)** in the middle phalanx until its drive end is flush with the resected bone surface.



5. Deliver the **Taper Lock Pin** into the proximal screw using the **Taper Delivery Tool**. Lightly tap the tool using a mallet to secure it within the screw. Note: Use the angled taper lock pin to place the toe in 10° plantar flexion. See Step 1 above.



6. Grasp the middle phalanx and place the **Distal Screw** over the exposed half of the taper lock pin on the proximal screw. **Tip:** Axial position of the proximal and distal screws can be adjusted to achieve the desired bone to bone apposition. Each 90° clockwise rotation of the **Screw Driver** will advance the screw further into the bone by 0.5 mm, and vice versa.



7. Use firm pressure to press the middle phalanx onto the proximal phalanx once desired bone to bone apposition is achieved. Place **Thimble** over the toe and lightly tap it using a mallet to secure the taper lock pin within the screws.
8. Physically probe the PIPJ to check for stability and screw interface retention following final implant delivery. Verification via intra-operative fluoroscopy is recommended.

The basic outline of the Implant Removal Protocol is as follows:

1. In case of a non-union, open the joint space using a transverse or longitudinal incision.
2. Distract the phalangeal bones using standard osteotomes to separate the implant components and expose the opposing joint surfaces.
3. Implants can be removed using the **Screw Driver** if permissible, or with the use of surgical pliers.
4. A corticotomy or dorsal window can be created to expose the implant. Following exposure, elevate the tip proximally with a curette or elevator, grasp and twist or pull out directly.

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Patents Pending

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