MAXLOCK EXTREME™ SYSTEM
Instructions for Use

1) DEVICE DESCRIPTION

a) The MaxLock Extreme™ System with Tribrid™ Technology consists of various size plates and screws used to stabilize and aid in the fusion or repair of fractured small bones. The plates are offered in different lengths and sizes. The screws are offered in different diameters and lengths. All implantable components are made from Ti-6AL-4V ELI Titanium Alloy per ASTM F-136 or PEEK-OPTIMA® polymer from INVIBIO® per ASTM F-2026.

b) All independent caddies must be used in conjunction with a MaxLock Extreme System implant and instrument tray. The Ankle Fusion Anterior, Lateral and Lateral TTC plate caddies must also be used in conjunction with the MaxTorque™ Cannulated Screw System implant and instrument tray. Consult the MaxTorque Cannulated Screw system labeling for Cannulated Screw system-specific instructions for use

c) The sterilization container(s) for the MaxLock Extreme System may be configured with the MaxTorque 4.0mm cannulated screw caddy. Consult the MaxTorque Cannulated Screw system labeling for MaxTorque specific instructions for use.

i) Follow the recommended sterilization cycle parameters in this document for all configurations of the MaxLock Extreme sterilization containers.

ii) The MaxTorque cannulated screws are not designed to be placed through the screw holes in the MaxLock Extreme plates.

2) INDICATIONS FOR USE

a) The MaxLock Extreme System is indicated for:

i) The MaxLock Extreme Universal Plating module is indicated for use in adult or pediatric patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically prepared (osteotomy) for correction of deformity or arthrodesis. Indications for use include internal fixation of the tibia, fibula, femur, humerus, ulna, radius, and bones in the hand, wrist, foot and ankle.

ii) The MaxLock Extreme Clavicle Plating module is indicated for fractures, fusions and osteotomies of the clavicle and bones in the hand, wrist, foot and ankle.

iii) The MaxLock Extreme Foot Plating module is indicated for fractures, fusions and osteotomies of bones in the hand, wrist, foot and ankle in pediatric and adult patients.

iv) The MaxLock Extreme Distal Radius Plating module is indicated for fractures and osteotomies of the distal radius in adult patients.

3) CONTRAINDICATIONS

a) Cases where there is an active infection.

b) Cases with malignant primary or metastasis tumors which preclude adequate bone support or screw fixations, unless supplemental fixation or stabilization methods are utilized.

c) Conditions which tend to retard healing, such as, blood supply limitations, previous infections, etc.

d) Insufficient quantity or quality of bone to permit stabilization of the fracture complex.

e) Conditions that restrict the patient's ability or willingness to follow post-operative instructions during the healing process.

f) Foreign body sensitivity – where material sensitivity is suspected, appropriate tests should be made and sensitivity ruled out prior to implantation.

g) Cases where the patient is obese.

4) DIRECTIONS FOR USE

a) An appropriately sized plate is placed such that the screw holes span the fracture or osteotomy site while it is okay to have some screw holes positioned over that site, the plate should be fixed to the bone via screws on both sides. Note that when using plates with center holes, they may be placed on either side of the fracture site. The correctly sized drill bit and guide sleeve are utilized to produce holes for the screw to be inserted. Locking drill guides must be used when inserting a locking screw so that the drill angle is correct. Screws are inserted with care to ensure that the threaded portion of the screw does not span the implant/bone interface or a fracture surface. When screws are used for adjuvant fixation with bone cement, the screws must be inserted while the cement is in the doughy stage for optimal results. Additionally, when used in this application, the screw heads must be fully seated into the recess of the plate when tightened. Detailed surgical techniques for implantation surgeries are available.

5) WARNINGS AND PRECAUTIONS

a) Surgical technique and training

i) Read all instructions carefully. Failure to properly follow the instructions, warnings, and precautions may lead to serious surgical consequences or injury to the patient.

ii) Surgical implants must never be reused. Implants are ONE TIME USE devices. An implant once used should be discarded. These implants must not be re-sterilized or reused after contact with body tissues or fluids. Reuse may damage or compromise device performance and patient safety. Reuse can cause cross-contamination leading to patient infection.

iii) Preoperative and operative procedures, including knowledge of surgical technique, stable anatomic reduction and proper selection and placement of the implants are important considerations in the successful utilization of temporary internal fixation devices. See the surgical technique for specific surgical procedures.

iv) CORRECT HANDLING OF IMPLANT IS EXTREMELY IMPORTANT. Avoid contouring metallic implants whenever possible. If necessary or allowed by design, the device should not be bent sharply, reverse bent, notched or scratched. All of these operations can produce defects in the surface finish and internal stress concentrations, which may become the focal point for eventual failure of the device. DO NOT BEND SCREWS.

v) If bending a plate through a threaded locking hole, the utilization of non-locking screws are recommended to insert through those particular holes, as the amount of deformation may inhibit threaded screws from fully seating due to deformation incurred.

vi) If metal screws, wire bands or other metallic devices are to be used together with the plates, all such devices should be manufactured from a metal that has a similar composition to avert possibility of galvanic corrosion or other metallic reactions.

b) Implant Sizing

i) CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT. The potential for success in fracture fixation is increased by the selection of the proper size, shape and design of the implants. The patient's anatomy will determine the size of the plate and screws to be used. The size and shape of the anatomy presents limiting restrictions on the size and strength of the implants.

c) Patient Selection

i) When evaluating patients for orthopedic device application, the patient's weight, occupation, activity level and any degenerative diseases are of extreme importance to the eventual success of the procedure. These conditions must be evaluated as part of the preoperative planning. Conditions of senility, mental illness, alcoholism, tobacco, or drug abuse must also be taken into consideration.

ii) Final treatment decision is at the discretion of the physician and patient.

d) Use in Pediatric Patients

i) When indicated for pediatric patients, avoid placing the plate over an unfused growth plate.

e) Device Compatibility

i) It is not recommended to use other manufacturers' implants in any assembly or construct application in conjunction with Tornier, Inc implants.

f) Post-Operative Care

i) NOTE: Postoperative care is extremely important. The patient must be warned that noncompliance with postoperative instructions could lead to breakage of the implant requiring revision surgery to remove the device.

ii) The use of plates provides the orthopedic surgeon a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are intended as a guide to normal healing and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delayed unions or nonunions in the presence of load bearing or weight bearing might eventually cause the implant to break due to metal fatigue. All metal surgical implants are subject to repeated stress in use, which can result in metal failure.

iii) Failure to immobilize a delayed union or nonunion of bone will result in excessive and repeated stresses which are transmitted by the body to any temporary internal fixation device prior to the healing of the fracture. Due to normal metal fatigue, these stresses can cause eventual bending or breakage of the device. Therefore, it is important that immobilization of the fractures site is maintained until firm bony union (confirmed by clinical and radiographic examination) is established.

iv) NO PARTIAL WEIGHT BEARING OR NONWEIGHT BEARING DEVICE CAN BE EXPECTED TO WITHSTAND THE UNSUPPORTED STRESSES OF FULL WEIGHT BEARING. Until firm bone union is achieved, the patient should employ adequate external support and restrict physical activities, which would place stress upon the implant or allow movement at the fracture site and delay healing.

v) Detailed written instructions on the use and limitations of the device should be given to the patient. If partial weight bearing is recommended or required prior to fusion, the patient must be warned that bending or breakage of the device are complications which may occur as a result of the weight bearing or muscle activity. An active, debilitated or demented patient who cannot properly utilize weight support devices may be particularly at risk during postoperative rehabilitation.

g) Removal of the Device

i) While the surgeon must make the final decision on implant removal, whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished, particularly in younger and more active patients.

ii) In the event that the device must be removed, select the appropriate instrumentation, and remove all components of the device.

h) Disposal of the Device

i) Upon removal of implant(s), dispose of as a biohazard material.

i) Magnetic Resonance Imaging (MRI) Safety and Compatibility

i) This product has not been evaluated for safety and compatibility or tested for heating or migration in the MR environment.

ii) This product has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of this product in the MR environment is unknown. Scanning a patient who has this device may result in patient injury..

j) Loosening, bending, cracking or fracture of the plate or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures.

k) Loss of anatomic position with nonunion or malunion with rotation or angulation.

l) Infection, both deep and superficial.

m) Allergies and other reaction to the device material.

6) CLEANING AND STORAGE

a) Store in a cool, dry place.

b) Instruments are provided non-sterile, and must be cleaned before use.

i) Completely disassemble instruments, as appropriate.

ii) Rinse instruments in lukewarm tap water until all visible soil is removed.

iii) Fully immerse instruments in enzymatic detergent for a minimum of 10 minutes. Thoroughly brush the instruments using a soft-bristled brush, assuring all hard to reach areas and cannulas are accessed. A syringe or pipe cleaner may be used if applicable.

iv) Rinse instruments in lukewarm tap water until all detergent residues are removed.

v) Fully immerse instruments in a neutral pH (7.0) or mild detergent. Thoroughly brush the instruments using a soft-bristled brush, assuring all hard to reach areas and cannulas are accessed.

vi) Rinse instruments in lukewarm tap water until all detergent residues are removed.

vii) Visually inspect the instruments under room lighting conditions to ensure instruments are suitable for use and free of debris prior to sterilization.

8) STERILIZATION

a) Implants and instruments are supplied non-sterile and must be sterilized before use.

i) Do not reuse implants; they are ONE TIME use only.

ii) Do not reuse instruments that are labeled as ONE TIME use.

iii) Do not use the device if damage is present such as nicks, gouges, or scratches.

b) Please note that the sterilization parameters are different depending on the configuration or type of MaxLock Extreme Tray being utilized. Ensure that you are utilizing the appropriate sterilization cycle.

c) Sterilize with steam sterilization. The following steam sterilization cycles are recommended based upon validation of a single tray wrapped in an FDA cleared sterilization wrap. Flash sterilization is NOT recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: 2006 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Sterilization cycles beyond the prescribed parameters must be validated independently by the facility. Each facility's process parameters should be validated for the type of sterilization equipment and product load configuration.

MXE-800-001 Rev 6

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"Caution: Federal law restricts this device to sale by or on the order of a physician". Various aspects of the MaxLock Extreme™ System including the plates, screws, instruments, and the design method are covered by multiple patents pending or issued patents in the United States and other jurisdictions.

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d) **MAXLOCK EXTREME TRAY – STANDARD**
   i) **Note that not all MaxLock Extreme Caddies are intended to be placed in this tray. Refer to the list below for a complete list of caddies that can be placed in this tray**
   ii) Only the following caddies may be placed in this tray and are covered by this sterilization cycle.
      (1) MTP, TMT, and OrthoLink Caddy
      (2) Universal Plate Caddy
      (3) Distal Fibula Plate Caddy
      (4) Distal Tibia Plate Caddy
      (5) Clavicle Plate Caddy
      (6) EdgeLock Plate Caddy
      (7) OrthoLink Osteotomy Plate Caddy
      (8) Variable Screw Caddy
      (9) CalcLock Extreme Caddies (2)
      (10) Utility Caddy
   iii) All other caddies must be sterilized independently or in their respective tray listed below.
   iv) Recommended cycle: eight minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   v) Recommended dry time: sixty minutes.
   vi) In addition to the FDA cleared sterilization wrap, the tray can also be sterilized using the above parameters within an FDA cleared Aesculap steam sterilization tray with filter.

e) **CALCLOCK EXTREME TRAY**
   i) Please note that these are the sterilization parameters for CalcLock Extreme Tray and its associated caddies. For the sterilization parameters for the independent CalcLock Extreme caddies (2), please consult the MaxLock Extreme Auxiliary Tray, MaxLock Extreme Standard Tray, or Independent Caddies sterilization parameter sections.
   ii) Recommended cycle: ten minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   iii) Recommended dry time: fifty-five minutes.

f) **DR LOCK EXTREME TRAY**
   i) Please note that these are the sterilization parameters for DR Lock Extreme Tray. The caddies are not intended to be placed in the standard MaxLock Extreme Tray.
   ii) Recommended cycle: ten minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   iii) Recommended dry time: fifty-five minutes.

g) **EDGELOCK KIT**
   i) Please note that these are the sterilization parameters for EdgeLock Kit and its associated caddies and instrumentation. For the sterilization parameters for the independent EdgeLock caddy, please consult the MaxLock Extreme Auxiliary Tray, MaxLock Extreme Standard Tray, or Independent Caddies sterilization parameter sections.
   ii) Recommended cycle: four minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   iii) Recommended dry time: thirty minutes.

h) **FRACTURE SET**
   i) Please note that these are the sterilization parameters for Fracture set and its associated caddies and instrumentation. .
   ii) Recommended cycle: four minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   iii) Recommended dry time: thirty minutes.

i) **MIDFOOT SET**
   i) Please note that these are the sterilization parameters for Midfoot set and its associated caddies and instrumentation. For caddies used outside of the Midfoot Set, please consult the appropriate tray or Independent Caddies sterilization parameters section.
   ii) Recommended cycle: four minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   iii) Recommended dry time: thirty minutes.

j) **MAXLOCK EXTREME SPECIALIST & AUXILIARY TRAYS**
   i) All MaxLock Extreme Caddies that will fit in this tray are covered by this sterilization cycle.
   ii) Recommended cycle: four minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   iii) Recommended dry time: sixty minutes.

k) **MAXLOCK EXTREME ANKLE FUSION & ELBOW PLATING SYSTEM**
   i) Please note that these are the sterilization parameters for the Ankle Fusion and Elbow Plating Systems and its associated caddies and instrumentation. For caddies used independent of the Systems, please consult the appropriate tray or Independent Caddies sterilization parameters section.
   ii) Recommended cycle: four minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   iii) Recommended dry time: sixty minutes.

l) **INDEPENDENT CADDIES**
   i) The following are the sterilization parameters for **ALL** caddies sterilized independent of the tray
      (1) Recommended cycle: four minutes in a 270°F (132°C) pre-vacuum steam sterilization.
      (2) Recommended dry time: thirty minutes.

9) LOANER AND CONSIGNMENT SET SHIPMENTS
   a) Before returning to the Tornier Company, the instrumentation (entire box or isolated instrument) must be pre-disinfected, cleaned and sterilized according to above mentioned recommendations and be correctly packaged. Respect the positioning of the instrumentation (instruments, packaging trays and baskets) in the corresponding container.

10) RATCHETING HANDLE CARE
   a) The following guidelines are intended to provide care and handling instructions for stainless steel ratcheting handles. These guidelines are not intended for use with electrical, pneumatic or powered surgical instruments.
   b) All instruments are shipped in a *NON-STERILE* condition and *MUST* be cleaned, lubricated, and autoclaved prior to use.
   c) CLEANING
      i) MANUAL CLEANING
         (1) Clean instruments as quickly as possible after each use. It is important not to allow blood or debris to dry on the instruments. If cleaning must be delayed, store the ratcheting driver in a covered container with the appropriate detergent or cleaning solution to delay drying. Do not use high concentrations of chlorine bleach on stainless steel instruments or pitting will occur. Do not use abrasive pads or cleansers. This will scratch the surface of the handle and remove the protective coating. This can lead to corrosion, dirt collection, and water deposits. Sort instruments by similar metal for subsequent processing to avoid electrolytic deposition (galvanic corrosion) due to contact between dissimilar metals.
      ii) ULTRASONIC CLEANING
         (1) Ultrasonic cleaners are effective when used per the manufacturer's instructions with specially formulated detergents. It is recommended that all visible blood and debris be removed from the instrument prior to ultrasonic cleaning. Sort instruments by similar metal for subsequent processing to avoid electrolytic deposition (galvanic corrosion) due to contact between dissimilar metals.
   d) LUBRICATION
      i) Ultrasonic cleaning effectively removes all lubricant, so it is important to re-lubricate each handle immediately after cleaning. The use of an antibacterial, lubricating rust inhibitor is highly recommended. This water-soluble lubricant should be mixed in a bath solution made with demineralized water. Instruments should be immersed in this solution for 30 seconds and allowed to drip dry. This allows for the formation of a lubricant film that will remain throughout the sterilization process and this film will continue to protect the handles during storage. This process guards instruments from staining and corrosion during sterilization and storage.
   e) AUTOCLAVING
      i) Staining and spotting may result if residual chemicals are not completely rinsed from instruments prior to steam sterilization. It is imperative to follow the proper sterilization and drying cycles outlined in the enclosed equipment literature. Failure to follow the provided instructions may result in incomplete sterilization, excess moisture formation, and water spotting.
   f) RINSING THE HANDLE
      i) Avoid using tap water for rinsing the driver. The minerals in tap water can cause driver discoloration or staining. Use demineralized water for rinsing in order to prevent spotting. If tap water must be used for the final rinsing, dry the instruments immediately to prevent staining.
   g) MAINTAINING CORROSION RESISTANCE
      i) Metallic components of the ratcheting handles are made of corrosion resistant specialty stainless steels. These steels form a passive oxide layer on the surface to protect them against corrosion. In order to maintain the quality of this protective layer, it is imperative to use and maintain the ratcheting handle properly. Failure to follow the provided instructions can lead to rust formation, which reduces the life of the instrument and the corrosion resistance.
   h) CALIBRATING TORQUE LIMITING HANDLE
      i) Calibration cycles are dependent on product handling and the frequency of use. It is recommended to return the product for torque verification or adjustment after one of the following are met:
         (1) Six months of use
         (2) 200 autoclave cycles
         (3) Approximately 3000 actuations (Clicks)
   i) IF AT ANY TIME A DEVICE SEEMS TO BE MALFUNCTIONING, REMOVE IT FROM SERVICE IMMEDIATELY AND RETURN IT TO TORNIER, INC. FOR RECALIBRATION OR REPLACEMENT
   j) These guidelines are written to provide general information on the care and cleaning of surgical instruments. Attention has been paid to chemical and corrosion contacts that may inadvertently degrade, corrode, or otherwise shorten the expected life of hand held surgical instruments. These guidelines are not all-inclusive and do not outline every possible chemical contact or reaction that may occur while handling or cleaning.

11) LIMITED WARRANTY
   a) Tornier, Inc. warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse, or improper handling of the product subsequent to receipt by the purchaser. Tornier, Inc. does not warrant the outcome of the surgical procedure.

Symbol	Meaning
REF	Catalog Number
LOT	Batch Code
EC REP	Authorized Representative of the European Community
	Caution, Consult Accompanying Documents
	Consult Instructions for Use
	Do Not Reuse
	Not Made with Natural Rubber Latex
	Do Not Use if package is damaged
	Non-Sterile
Rx Only	Caution: Federal Law (USA) restricts this device to sale by or order of a physician
	Manufacturer

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