MAXLOCK EXTREME™ System

Instructions for Use

1) DEVICE DESCRIPTION

a) The MaxLock Extreme™ System with Trubolt® 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 diameters. The screws are offered in different diameters and lengths. All implantable materials are composed of Ti-6Al-4V ELI Titanium Alloy per ASTM F-136 or PEEL-OPTIMA® polymer from INVIBIO® per ASTM F-2026.

b) All independent caddies are used with the MaxLock Extreme implant and instrument tray. The Axle Fusion, Lateral and Lateral TCT 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 containers 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.

2) INDICATIONS FOR USE

a) Indications for use include adult or pediatric patients as indicated for pelvic, small and long bone fracture fixation and fixation of bones that have been surgically fragmented for correction of deformity or articular malalignment. Indications for use include internal fixation of the tibia, femur, humerus, ulna, radius, and bones in the hand, wrist, foot and ankle.

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

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

d) The MaxLock Extreme Distal Radius Plating System 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 fixtures, unless supplemental fixation or stabilization methods are utilized.

c) Conditions which tend to produce metal fatigue, including infections, 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 screws hole span the fracture or osteotomy site while it is okay to have some screw hole positions 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, and the screws are utilized to produce holes for the screws to be inserted. Locking drill guides must be utilized 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 spin the implant/bone interface or a fracture surface. When screws are used for adjacent fixation with bone cement, the screws must be inserted while the cement is in the doughy stage of development. Additive, when used in this application, to the cement head must be fully seated into the recess of the plate when tightened. Detailed surgical technique for implantation of plates is available.

5) WARNINGS AND PRECAUTIONS

a) Surgical technique and training

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

c) Surgical implants must never be reused. Implants contaminated with ONE TIME USE devices. An implant once used should not be re-sterilized or reused after contact with body tissues or fluids. Reuse may damage or compromise device performance and may lead to patient infection.

3) Preparatory and operative procedures, including knowledge of surgical technique, stable anatomic and proper selection and placement of the implants are important considerations in the surgical technique for specific surgical procedures.

4) DIRECT HANDLING OF STERILIZED COMPONENTS IS EXTREMELY IMPORTANT. Avoid contacting metallic implants while possible. If necessary or allowed by design, the device should not be bent sharply, reverse bent, notched or cracked. 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 prevent breakage of the device. Deformation may inhibit threaded screws from fully seating due to deformation caused.

vi) If metal screws, wire bands or other metallic devices are to be used together with the plate, such devices should be removed, as they have a similar composition to avoid potential of galvanic corrosion or other metallic reactions.

vii) Implant Sizing

i) When evaluating patients for orthopedic device application, the patient’s weight, occupation, activity level and other specific factors influence 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.

iii) Use in Pediatric Patients

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

ii) Device Compatibility

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

v) Post-Operative Care

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

ii) The use of postoperative pain medications can cause a means of bone fixation and helps generally in the management of fractures and reconstructive surgeries. These implants are indicated as a guide to bone alignment and are NOT intended to replace normal body structure or bear the weight of the body in the presence of incomplete bone healing. Delays unions or nonunions in the presence of load bearing or weight bearing devices can 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 prolonged bone stress, which are not compatible with internal fixation devices and therefore are not compatible with internal fixation devices 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 is maintained in the most stable and proper method until final union has been achieved.

iv) In certain cases, external fixation devices may be used as temporary internal fixation devices. See the surgical technique for specific surgical procedures.

v) Contraindications in the Successful Utilization of Temporary Internal Fixation Devices

i) Cases where there is an active infection.

ii) Cases where the patient is obese.

iii) Cases where there is an active infection.

iv) Cases where the patient is obese.

v) Contraindications in the Successful Utilization of Temporary Internal Fixation Devices

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d) 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.

- 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 Tibia Plate Caddy
  - (4) Distal Tibia Plate Caddy
  - (5) Clavicle Caddy
  - (6) EndoLink Plate Caddy
  - (7) OrthoLink Ankle Plate Caddy
  - (8) Variable Screw Caddy
  - (9) CalcLock Extreme Caddies (2)

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 hydraulic 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.

i) PRIOR TO USE

- Sterilize and package the instruments as described in the sterilization parameters section.
- Before placing the instruments in the tray, remove any excess moisture, soap, or lubricant from the instruments.
- Sort instruments by similar metal for subsequent processing to avoid electrolytic deposition (galvanic corrosion) due to contact between dissimilar metals.
- Do not use abrasive pads or cleansers. This can scratch the surface of the handle and remove the protective coating. This can lead to corrosion, dirt accumulation, and water spotting.

ii) STORAGE

- Store instruments in a dry, clean, and protected environment.
- Store instruments in a dust-free, clean, and well-lit area.
- Store instruments in a dark, cool, and dry area.

iii) STERILIZATION

- Use the appropriate sterilization cycle and parameters for the instruments being sterilized.
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iv) CLEANING

- Use a clean, dry, and soft cloth to clean the instruments after each use.
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v) DRYING

- Dry the instruments for at least thirty minutes or until dry to the touch.
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vi) LUBRICATION

- Lubricate the instruments with a water-soluble lubricant after each use.
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vii) RATCHETING HANDLE CARE

- Use a clean, dry, and soft cloth to clean the instruments after each use.
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viii) 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. ©2016 Wright Medical Group N.V., or its affiliates. All Rights Reserved.