MaxTorque™ Screw System
Instructions for Use

1) DEVICE DESCRIPTION

a) The MaxTorque™ Screw System consists of various size screws and washers used to aid in the repair of fractures, fusions, and osteotomies of small and long bones. The screws are offered in Ø2.5mm, Ø3.0mm, Ø3.2mm, Ø3.8mm, Ø4.0 mm, Ø4.5mm, Ø5.5mm, and Ø7.0mm diameters and several different lengths. All screws and washers are made from Ti-6AL-4V ELI Titanium Alloy per ASTM F-136.

2) INDICATIONS FOR USE

a) The MaxTorque™ Screw System is indicated for use in long and small bone fracture, fusion, and osteotomy fixation, which includes but is not limited to the following:

- Fractures of the tarsal and metatarsals
- Fractures of the olecranon, distal humerus
- Fractures of the radius and ulna
- Patellar fractures
- Distal tibia and pilon fractures
- Fractures of the fibula, medial malleolus, os calcis
- Tarso-metatarsal and metatarsal-phalangeal arthrodesis
- Metatarsal and Phalangeal osteotomies
- Osteochondritis dissecans
- Ligament fixation
- Other small fragment, cancellous bone fractures and osteotomies

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 screw is selected based on anatomical size and indication. A corresponding guide wire is then chosen and inserted using a wire driver. Upon verification of correct placement by fluoroscopy, use the corresponding depth gauge. Proceed by selecting the corresponding drill guide and bit. Place both drill guide and drill bit over the guide wire. Drill to desired depth. Then insert the screw with corresponding sized screw driver. Repeat as necessary. Detailed surgical techniques for using a counter sink or washer 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) NO METALLIC SURGICAL IMPLANT SHOULD BE REUSED. Any metal implant, once used, should be discarded. Even though it appears undamaged, it may already have small defects and internal stress patterns which may lead to fatigue failure.
   iii) Preoperative and operative procedures, including knowledge of surgical techniques, good reduction and proper selection and placement of the implants are important considerations in the successful utilization of temporary internal fixation devices. See the surgical techniques 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 appliance.
   v) If metal plates or other metallic devices are to be used together with the cannulated screws, 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 and indication will determine the size of the cannulated screw to be used. The size and shape of the human bones presents limiting restrictions on the size and strength of implants.
c) Patient Selection
   i) In evaluating patients for orthopedic appliance 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) 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 screws 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 non-unions 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 fatigue.
   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 roentgenographic examination) is established.
d) Post-Operative Care (cont.)
   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 firm by any union, 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 patient or a debilitated or demented patient who cannot properly utilize weight support devices may be particularly at risk during postoperative rehabilitation.

10801 Nesbitt Avenue South, Bloomington, MN 55437 Phone 952-921-7100 Fax: 952-236-4007

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5) WARNINGS AND PRECAUTIONS (cont.)

e) 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 more active patients.

f) Disposal of the Device
   i) Upon removal of implant(s), dispose of as a biohazard material.

g) Magnetic Resonance Imaging (MRI) Safety and Compatibility
   i) 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.

6) POSSIBLE ADVERSE AFFECTS

a) Loosening, bending, cracking or fracture of the screw or loss of fixation in bone attributable to nonunion, osteoporosis, markedly unstable comminuted fractures.
b) Loss of anatomic position with nonunion or malunion with rotation or angulation.
c) Infection, both deep and superficial.
d) Allergies and other reaction to the device material.

7) CLEANING AND STORAGE

a) Store in a cool, dry place.
b) The MaxTorque™ Screw System Instruments are provided non-sterile, and must be cleaned and sterilized 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 to ensure instruments are suitable for use and free of debris.

8) STERILIZATION

a) The MaxTorque™ Screw System screws are supplied non-sterile and must be sterilized before use.
   i) Do not reuse implants. They are one-time use only.
   ii) Do not use the device if damage is present such as nicks, gauges, or scratches.
b) Please note that the sterilization parameters are different depending on the configuration or type of MaxTorque Tray being utilized. Ensure that you are utilizing the appropriate sterilization cycle.
c) Sterilize with steam sterilization. The following steam sterilization cycle is recommended based upon validation of a single MaxTorque Screw System tray with an FDA cleared sterilization wrap and an FDA cleared steam sterilizer using strips and sutures. 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.

(1) MaxTorque™ Tray - *Standard*
   (a) Recommended cycle: eight minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   (b) Recommended dry time: forty minutes.

(2) MaxTorque™ Tray – *Lite*
(Standard configuration without the Ø4.0mm Instrument Tray and Washer Caddy, and with the square drive handle from the Ø4.0mm Instrument Tray placed in the tray base near the Ø7.0mm instruments)
   (a) Recommended cycle: four minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   (b) Recommended dry time: forty minutes.

(3) Mini MaxTorque™ Zero Profile Tray – *Standard (Ø2.5mm, Ø3.2mm, Ø3.8mm, and/or Ø4.0 mm screws)*
   (a) Recommended cycle: eight minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   (b) Recommended dry time: forty minutes.

(4) Mini MaxTorque™ Zero Profile Tray – *Lite (3-Layer Tray containing only two of the following drawers: Ø2.5mm, Ø3.2mm, Ø3.8mm, Ø4.0mm)*
   (a) Recommended cycle: four minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   (b) Recommended dry time: forty minutes.

(5) Mini MaxTorque™ Zero Profile Tray – *Non-Standard (Ø2.5mm, Ø3.0mm, Ø3.2mm, and Ø3.8mm screws)*
   (a) Recommended cycle: ten minutes in a 273°F (134°C) pre-vacuum steam sterilization.
   (b) Recommended dry time: sixty minutes.

(6) MaxTorque™ Auxiliary Screw Caddies
   (a) Recommended cycle: four minutes in a 270°F (132°C) pre-vacuum steam sterilization.
   (b) Recommended dry time: sixty minutes.

9) LOANER AND CONSIGNMENT SET SHIPMENTS

a) All instruments and implants must be placed back in their respective trays within their appropriate sterilization case and sterilized per the sterilization instructions above prior to shipping back to the manufacturer. Any implants or instrumentation damaged due to neglect from mishandling or mispackaging will be billed to the customer.

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

Manufacturer:
TORNIER, INC.
10801 Nesbitt Avenue South
Bloomington, MN 55437
USA
Tel: (952) 921-7100
Fax: (952) 236-4007

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