INSTRUCTIONS FOR USE
TriMed® Hand Plating System

Caution: Federal Law restricts this device to sale by or on the order of a Physician.

General:
The TriMed® Hand Plating System a is rigid fixation system consisting of plates and screws in various configurations, shapes and sizes. These devices are to be used as an aid to the treatment of certain types of fractures, fusions or osteotomies that lend themselves to the principle of plate and/or screw fixation. Like every type of orthopaedic implant, it cannot be assumed to be uniformly effective without risk. Use of these implants is not a substitute for normal tissue healing. The TriMed Hand Plates and Screws are designed to provide additional constraint of movement of a fractured, fused or osteotomized bone and are intended only as an aid to fix the fracture in place during the healing process.

Basic Design Features:
The TriMed Hand Plates and Screws are implants designed for fixation of certain fractures, fusions or osteotomies. Variation in implant size, diameter, and shape are intended to allow the implants to accommodate variations in patient size and sites of application. TriMed Hand Plates should only be used with the appropriate size TriMed Bone Screws.

TriMed Hand Plates and Screws are manufactured from pure titanium and titanium alloy (Ti-6Al-4V), which meet ASTM F67, Standard Specification for Unalloyed Titanium for Surgical Implant Applications, and ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications which are widely used for surgical implants with well-known biocompatibility.

Indications, Contraindications, Adverse Effects:
Patient selection and sound surgical principles apply to the use of the TriMed Bone Plates and Screws in a given clinical setting. The decision to use an implant as well as the size and shape of the implant used must be based on sound medical judgment that takes into consideration factors such as the circumstances and configuration of the injury.

As with plate and screw fixation in general, the surgeon must implement post-operative patient protocol measures to avoid excessive force on implant until bone healing has taken place. This includes protection of the fracture, fusion or osteotomy when appropriate, and instructions to the patient to avoid excess loading of the extremity until sufficient healing has taken place. Medical personnel are encouraged to contact their TriMed representative(s) if a more comprehensive understanding of the implant, instrument(s) or system usability is required.

Specific Indications:
TriMed Hand Plating System is intended for use in internal fixation of bones of the hand and wrist. Example of these procedures may include but are not limited to replantation, lag screw techniques, joint fusions, corrective osteotomies, and the treatment of fractures.

Contraindications:
1. Physical conditions that would eliminate or tend to eliminate adequate implant support or delayed healing, viz.: blood supply limitations, insufficient quality or quantity of bone, poor skin quality, previous or active infections, sepsis, metabolic diseases, etc.

2. Mental or neurologic conditions which tend to pre-empt the patient's ability or willingness to restrict activities during the healing period, viz.: Parkinson's disease, chronic alcoholism, Charcot's joints, drug abuse, mental illness, patient noncompliance, etc.

3. Foreign body sensitivity. Where material sensitivity is suspected, standard appropriate tests should be made prior to material selection or implantation.

4. Compromised skin. In the setting of profound compromised skin, any internal fixation device should be approached with extreme caution because of the increased risk of wound healing problems and infection.

Contraindications may be relative or absolute. Users of this device must carefully weigh the advantages against possible complications and consider the patient's entire clinical exam in addition to the items listed above.

Possible Adverse Effects:
In any surgical procedure, the potential for adverse reactions exist. Possible adverse effects particular to orthopaedic devices are listed below. These do not include all adverse effects which can occur with surgical procedures.

1. Loosening, bending, cracking or fracture of any component with or without loss of fixation in bone, possibly in association with blood supply limitations, insufficient quality or quantity of bone, osteoporosis, delayed union, nonunion, excess activity, or any of the factors listed previously.
2. Loss of anatomic position with resulting nonunion, malunion, or delayed union.
3. Bone loss due to stress shielding.
4. Pain, a feeling of malaise, or abnormal sensation due to the implant used.
5. Infections, both deep and superficial.
6. Hematoma.
7. Tendinitis or tendon rupture.
8. Soft tissue irritation and/or nerve damage due to surgical trauma
9. Complex regional pain syndrome.
10. Local bursitis and pain from prominent hardware.
11. Tissue reactions as the result of allergy or foreign body reaction. Allergic responses to metal components are rare.

The adverse effects listed here are not specific to the TriMed Hand Plates and Screws and are in principal observed with any implant. Promptly inform the TriMed Quality Department at quality@trimedortho.com if complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide TriMed with the device in a cleaned, disinfected condition per TriMed's cleaning and sterilization instructions. TriMed cannot accept any other returns of used implants.

Warnings and Precautions:
1. Use caution in the handling and storage of implants. Implants should be stored in a dry place at room temperature and stored away from corrosive agents and environments. If implants appear damaged, they should not be implanted.

2. Implantation in patients with the contraindications specified previously should be avoided. It is important to preoperatively assess the radiographic configuration of the fracture, fusion or osteotomy prior to considering implantation of this device. In addition, all other relevant medical and social factors should be considered in order to determine whether a patient is an appropriate candidate for this device.

3. Allergies to component materials should be considered and tested, if appropriate, prior to using this device. See material composition under general regulatory information section.

4. A full inventory of instruments and implants should be available prior to initiation of the surgical procedure. Components should be inspected and tested in trial assembly prior to implantation. Do not use any faulty, damaged, or suspect components.

5. Surgeons are advised to review the product-specific surgical technique prior to performing surgery. Surgeons should also be fully familiar with the biomechanics and surgical principles inherent to the use of this device, and proper selection and placement of the device are important considerations in successful utilization of this device. The use of undersized plates and screws in areas of functional stress may lead to implant fracture and failure.

6. Any adjacent soft tissue structures should be checked to ensure that abrasive rubbing against components will not occur.

7. Size and position of implants should be checked radiographically prior to completion of the surgical procedure.

8. These devices are intended for single use only. Violation of this could potentially result in loss of performance, function, fit or device failure, and could potentially result in infection.

9. TriMed Hand Plates are to be grasped using the forceps supplied with the system.

10. TriMed Hand Plates can be bent and contoured using the plate bender. Plates should not be bent near the locking screw hole, as it may distort the hole threads which prohibits insertion of the screw.

11. TriMed Hand Plates should not be repeatedly bent at the same location or bent to excessive angles as it may potentially lead to premature plate fatigue, loss of performance or breakage in situ.

12. TriMed Bone Screws are self-tapping. All self-tapping screws require a pilot hole be made in the bone prior to screw insertion. Drilling a pilot hole reduces the chance of fracturing the bone and reduces the level of torque required to drive screws. To reduce the potential for thermal necrosis, all pilot drills should be used at minimal RPM. Proper pilot drilling technique indicates that the drill point performs the cutting. Fault drilling causes that screws will not fit tightly into the bone or even strip in the bone. The surgeon must use drill fit the diameter of screws.

13. Use on TriMed Bone Screws in high density bone may lead to implant fracture or failure upon insertion.

14. TriMed Bone Screws must be inserted by hand, and are not advised to be placed under powered equipment. Possible risks using screws under power or excessive torque include stripping, bending, cracking or fracturing of the implant and/or instrument.

15. TriMed Hand Plates should only be used with the appropriate size TriMed Bone Screws. TriMed has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

16. TriMed Hand Plates and Screws, and other devices of dissimilar material should not be used together in or near the implant site. Dissimilar metals in contact with each other can accelerate the corrosion process due to galvanic corrosion effects. Do not mix different metal implants in the same construct.

17. Postoperatively and until healing is complete, fixation provided by this device should be considered as temporary and may not withstand weight bearing or other unsupported stress. The fixation provided by this device should be protected. The postoperative protocol prescribed by the surgeon should be strictly followed to avoid adverse stresses applied to the device.

18. Removal of TriMed Hand Plates and Screws may be warranted if deemed medically necessary (e.g. fractured implants) in order to avoid possible adverse effects. TriMed Hand Plates and Screw may be removed using a driver shaft and other instruments. Upon removal, implants should be inventoried and discarded. Do not reuse.

19. These devices have not been evaluated for safety and compatibility in the MR environment. The devices have not been tested for heating or migration in the MR environment.

Warnings and Precautions – Surgical Instruments:
Reference TriMed Surgical Instruments Instruction for Use (IFU);
(See IFU, LC-73-0004-014).

Recommendations for Cleaning and Sterilization:

TriMed products supplied in a non-sterile condition must be cleaned and steam sterilized prior to surgical use. Prior to cleaning and/or sterilization, remove and dispose all original disposable packaging (e.g. silicone sleeves, tip guards, pouches, bags, tubes, etc.) Component devices must be disassembled prior to cleaning, disinfection and sterilization.

Cleaning: Unused TriMed implants that have been soiled by blood, tissue, and/or bodily fluids or matter, must be processed in a timely manner according to the following cleaning procedures**.** Due to variations in conditions and environments, the user has final responsibility for the implementation and verification of procedures to achieve cleanliness.

1. Rinse the soiled device under lukewarm running tap water (22° - 43° C) for a minimum of two (2) minutes. Remove gross soil using a soft-bristled brush or clean, soft, lint-free cloth. Note: Remove additional soil from challenging design features (i.e. holes lumens, hinged/mating surfaces, interfaces, crevices, serrations) using common cleaning tools. Never use metal brushes or steel wool for cleaning.

2. Prepare an enzymatic cleaning solution using Steris® Prolystica® 2X Concentrate Enzymatic Presoak per the manufacturer's instructions.

3. Fully immerse the instruments in the fresh, newly prepared enzymatic cleaning solution and soak for twenty (20) to twenty-five (25) minutes.

4. Use a soft-bristled brush to thoroughly clean the submerged device paying particular attention to crevices, lumens, mated surfaces, and other hard-to-clean areas. Brush for a minimum of 15 seconds or longer if needed to remove debris. Lumens should be cleaned with a long, narrow, soft-bristled brush (i.e. pipe cleaner brush) if needed to remove debris. Note: The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid).

5. Remove the device from the cleaning solution and thoroughly rinse with lukewarm, running tap water (22° – 43° C) for a minimum of one (1) minute. After rinsing ensure debris is removed from the instrument. If debris remains, use a syringe to flush the device or repeat rinsing until debris is removed.

6. Prepare a newly-made enzymatic cleaning solution Steris® Prolystica® 2X Concentrate Enzymatic Presoak according to the manufacturer's instructions. Place all devices within a container with the enzymatic cleaning solution and place the container in the sonication unit.

7. Fully immerse the device in the fresh, newly prepared enzymatic cleaning solution. Actuate the joints, handles, and other movable device features to expose areas to the cleaning solution several times. Sonicate for ten (10) to fifteen (15) minutes.

8. Fully immerse the device in a basin with clean lukewarm tap water (22° - 43° C) for rinsing. Gently agitate the device for a minimum of one (1) minute. Actuate the joints, handles, and other movable device features to expose areas to the water several times. Pass a soft bristled brush through any crevices or lumens.

9. Repeat steps 7 and 8 with freshly prepared cleaning solution if there is a sign of blood or soil in the tap water bath.

10. Remove the devices from the rinse solution and thoroughly rinse with lukewarm reverse osmosis or distilled water (22° – 43° C) for a minimum of one (1) minute. After rinsing ensure debris is removed from the instrument. If debris remains, use a syringe to flush the device or repeat rinsing until debris is removed.

11. Dry the device using a clean, soft, lint-free cloth or clean compressed air. Visually inspect the device; no visible soil should be left on the device. Note: Thorough drying of devices prevents corrosion from mineral content, condensate and residual agents.

Inspection, Assembly and Maintenance: After cleaning, TriMed implants are to be inspected for damage, wear, contamination and malfunctioning components. In case of visible residues, implants must be cleaned again.

1. The user is responsible for sorting out damaged and contaminated implants. Damaged implants must be brought to the attention of the TriMed representative(s).

2. Final inspection can comprise of, but not limited to,
    a. Cleanliness; absent of visible resides
    b. Visual intactness / physical integrity
    c. Operability of component parts, if applicable

Sterilization: TriMed recommends the following sterilization procedures for non-sterile implants and re-usable instruments. Due to variations in conditions and environments, the user has final responsibility for the implementation and verification of procedures to achieve sterility.

1. Place clean and unused implants and screws into the designated slots of the designated caddies. Disassemble instruments and place inside the designated caddy. Carefully close the caddy covers.

2. Place properly cleaned and dried instruments into the designated slots inside the sterilization tray. Disassemble instruments and place components inside sterilization tray. Where possible, hinged instruments should be in the open position.

3. Place the implant and screw caddies into the designated locations inside the sterilization tray. Carefully close the implant tray and clamp to seal.

4. Wrap the instrument tray with commercially available CSR wrap.

5. Place wrapped instrument tray in steam sterilizer, sterilize for 4 minutes in 132° C pre-vacuum cycle with 20-minute dry time.

6. Upon cycle completion, remove the wrapped instrument tray from sterilizer and place tray on a padded surface to prevent condensation during cooling.

7. Store the sterilized instrument tray in a clean and dry area.

General Regulatory Information

Material Composition (nominal values by % weight):

1. Material composition for Titanium-6 Aluminum-4 Vanadium ELI medical grade implant Titanium: Nitrogen (0.05%), Carbon (0.08%), Hydrogen (0.012%), Iron (0.25%), Oxygen (0.13%), Aluminum (5.5-6.50%), Vanadium (3.5-4.5%), Titanium (balance).

2. Material composition for Unalloyed (Pure) Titanium: Nitrogen (0.03%), Carbon (0.08%), Hydrogen (0.015%), Iron (0.30%), Oxygen (0.25%), Titanium (balance)

Product Labeling:

For product shipped, the following symbols may be indicated on the labels placed on the packaging:

Symbol	Symbol Description
	Catalog Number
	Lot Number
	Date of Manufacture
	Manufacturer
	Single Use Only. Do Not Re-use.
	Non-Sterile
	Consult Instructions for Use
	Caution
	Caution: Federal law restricts this device to sale by or on the order of a physician

See trimedortho.com for all listed patents

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