INSTRUCTIONS FOR USE
TriMed® Large Compression Screws

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

General:
The TriMed® Large Compression Screws are devices which are to be used as an aid to the treatment of certain types of fractures that lend themselves to the principle of 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 Large Compression Screws are designed to provide additional constraint of movement of a fractured bone and are intended only as an aid to fix the fracture in place during the healing process.

Basic Design Features:
The TriMed Large Compression Screws are implants designed for screw fixation of certain fractures. Variation in implant size, diameter, and shape are intended to allow the implants to accommodate variations in patient size and sites of application. TriMed Large Compression Screws are manufactured from implantable medical grade titanium or 316L medical grade implant quality stainless steel. TriMed Large Compression Screws should only be used with the appropriate instruments that are intended for their use.

Indications, Contraindications, Adverse Effects:
Patient selection and sound surgical principles apply to the use of the TriMed Large Compression 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. Specific fractures with configurations that would otherwise lend themselves to the general principle of bone screw fixation with this class of implants may be appropriate for use with this device.

As with screw fixation in general, the surgeon should take measures to avoid excessive force on implants until bone healing has taken place. This includes protection of the fracture 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:
The following fracture configurations may be applicable for treatment using the TriMed Large Compression Screws:

1. Fractures of the extremities amenable to screw fixation where the size, shape, and location of the fractured bone are appropriate for the specific implant(s) being used.
2. Fracture fixation of large bone and large bone fragments, as well as fractures of the calcaneus, talus, tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones.

Contraindications:
1. Physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing, viz.: blood supply limitations, insufficient quality or quantity of bone, poor skin quality, previous infections, 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 or retardation, patient noncompliance, etc.

3. Foreign body sensitivity. Where material sensitivity is suspected, standard appropriate tests should be made prior to material selection or implantation. In particular, the physician should be aware that some implants may be made from a material containing nickel, and should use sound medical judgment if nickel allergy or hypersensitivity is suspected.

4. Skin atrophy. In the setting of profound skin atrophy, 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. Use 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 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. Infections.
4. Hematoma.
5. Stiffness of the adjacent joint with or without degenerative changes.
6. Tendinitis or tendon rupture.
7. Scarring.
8. Reflex sympathetic dystrophy.
9. Local bursitis and pain from prominent hardware.
10. Allergic responses to metal components are rare. Some of these implants may contain nickel, and as with any implant, they should be tested preoperatively if indicated.

The adverse effects listed here are not specific to the TriMed Large Compression 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. Cutting, bending, or scratching the surface of metal components impairs the strength and fatigue life of the implant. Implants should be 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 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 tested in trial assembly prior to implantation.

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.

6. Use caution during insertion of the guide pin and screw to avoid excessive torque or bending loads which can impair the strength and fatigue life of the implant and potentially result in failure.

7. An adequate countersink in the bone must be prepared for complete seating of the head of the TriMed Large Compression Screw to prevent soft tissue irritation from protrusion of the head of the screw and excessive torque on the screw during insertion.

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

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

10. 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.

11. TriMed Large Compression Screws should be inserted by hand, and are not advised to be placed under powered equipment. Possible risks using screws under power include stripping, bending, cracking or fracturing of the implant and/or instrument. For screws where power equipment may be used, the surgeon must carefully control of the speed and power of insertion. It is the responsibility of the surgeon to ensure safe use.

12. TriMed Large Compression Screws should only be used with the appropriate TriMed Large Compression Screw instrumentation. TriMed has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

13. 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.

14. Removal of TriMed Large Compression Screws may be warranted if deemed medically necessary in order to avoid possible adverse effects.

15. 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 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.

Doc. No.: LC-73-0004-010 Rev. B (Feb-19)

4. Use a soft-bristled brush to gently 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 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 an 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 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.

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.

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 316L medical grade implant stainless steel: Carbon (0.030%), Manganese (2.00%), Phosphorous (0.025%), Sulfur (0.010%), Silicon (0.75%), Chromium (17.00-19.00%), Nickel (13.00-15.00%), Molybdenum (2.25-3.00%), Nitrogen (0.10%), Copper (.050%), Iron (balance).

2. 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).

Product Labeling:

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

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

TriMed®

See trimedortho.com for all listed patents

TriMed, Inc.
27533 Avenue Hopkins
Santa Clarita, CA 91355, USA
(661) 255-7406 / (800) 633-7221