INSTRUCTIONS FOR USE
TriMed® Surgical Instruments

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

General:
TriMed® Surgical Instruments are an array of generic and unique instruments designed specifically for orthopedic surgery. Such tools facilitate orthopedic surgeons to achieve, enable or expedite specific tasks related to surgical techniques and implant systems. TriMed Surgical Instruments are reusable or single-use devices. Generally, single-use devices perform drilling, sawing, cutting, and boring occurring within musculoskeletal structures. Reusable instruments perform other functions occurring outside musculoskeletal structures such as: fastening, bending, crimping, impacting, inserting/extracting/retracting, grasping, repositioning, aligning/aiming, trial/templating, tensioning, torqueing, cutting, clamping, elevating, and gauging. TriMed Surgical Instruments and implants are supplied to the user in a system-dedicated, non-sterile rigid instrument tray that accommodates the specific TriMed devices to be processed for inspection, cleaning, sterilization, transportation and storage.

Basic Design Features:
TriMed Surgical Instruments are manufactured from medical-grade stainless steel, titanium, aluminum, nickel titanium and/or common medical device polymers. Instruments may be hand-held, manually operated or attached to powered equipment, where applicable. TriMed Surgical Instruments should only be used with the appropriate TriMed devices (i.e. interacting instruments and implants) per surgical technique.

Indications, Contraindications, Adverse Effects:
TriMed Surgical Instruments shall only be used for their intended purpose. Surgical technique provides method of application for principal instrumentation. The decision to use an instrument must be based on sound medical judgement that takes into consideration factors such as surgical application, physical and mechanical properties. Medical personnel are encouraged to contact their TriMed representative(s) if a more comprehensive understanding of the instrument mechanics or its method of use is required.

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

Compromised mechanical, physical or chemical characteristics resulting in,

a. Patient related
   i. Bone damage or necrosis
   ii. Inflammatory, foreign body or allergic reaction
   iii. Infection
b. Device related
   i. Loosening, decoupling, bending, stripping, cracking or fracturing of device
   ii. Breakage resulting in device fracture fragments within wound
   iii. Loss or lack of function or connecting mechanisms

The adverse effects listed here are not specific to the TriMed Surgical Instruments and are in principal observed with any orthopedic or surgical instrument. Promptly inform the TriMed Quality Department at quality@trimedortho.com if complications occur in connection with the surgical instruments used. In the event of premature failure of an instrument 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.

Warnings and Precautions:
All Instruments and Trays:

1. The TriMed Surgical Instruments and instrument trays are provided to the user facility in a non-sterile condition. These instruments must be cleaned and sterilized, according to these instructions, prior to each use.

2. Refer to instrument label to determine whether an instrument is single use or reusable. Single use instruments are labeled with a single-use only "do not reuse" symbol.

3. Surgeons are advised to review the product-specific surgical technique prior to performing surgery. Surgeons should also be fully familiar with the instrument, the method of application, and surgical technique. Proper handling and use of the device are critical considerations in successful utilization of this device.

4. TriMed Surgical Instruments shall not be used for any purpose other than their intended use.

5. TriMed Surgical Instruments should only be used with the appropriate TriMed devices (i.e. interacting instruments and implants). TriMed has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

6. Only devices manufactured and/or distributed by TriMed should be included in the TriMed instrument trays. The following validated reprocessing instructions are not applicable to TriMed instrument trays that include devices that are not manufactured and/or distributed by TriMed.

7. Both reusable and single use instruments are subject to wear with repeated use. Inspect instruments prior to use to verify condition and do not use if damaged or worn.

8. Instrument breakage or damage can occur when an instrument is subjected to excessive or inappropriate loads and/or angles for the specific application, blunt force, excessive speeds, dense bone, improper use (e.g. off-axis drilling/sawing/boring from guide trajectory), or unintended use. Cutting, bending, or scratching the surface of metallic or polymer components may impair the strength and life of the device.

9. Proper handling and use of devices can be ensured by referring to color coding and informational laser marking on interacting instruments, per surgical technique.

10. Instrument (metal or polymer) tray damage can occur when subject to excessive loads or inappropriate handling. Inspect trays for excessive surface damage, distortion or warping.

11. TriMed Surgical Instruments (e.g. depth gauge stylus, templates) should not be repeatedly bent at the same location or bent to excessive angles as it may potentially lead to premature fatigue, loss of accuracy/calibration or breakage *in situ*.

12. A full inventory of instruments and implants should be available prior to initiating a surgical procedure. Components should be tested in trial assembly prior to the actual operation.

13. Do not allow biologic soil to dry on contaminated devices. All subsequent cleaning and sterilization steps are facilitated by not allowing blood, body fluids and tissue debris to dry on the instruments or trays.

14. Do not place soiled instruments back into the metal/polymer tray prior to proper cleaning per TriMed's cleaning instructions. Do not clean soiled instruments while in tray. Soiled trays must be stripped of its clean, unused devices.

15. Use caution in the handling and storage of instruments and instrument trays. After sterilization, reusable instruments should be stored in the sterilization wrapped rigid container in a dry and dust-free environment. Instruments and instrument trays should be stored away from environments and agents that may cause contamination and deterioration.

16. TriMed instrument trays are intended to be used with a sterile barrier system (e.g. sterile wraps) in order to maintain sterility until opened. Unwrapped instrument trays do not maintain sterility.

17. Do not externally stack TriMed instrument trays when applying sterilization wrap and when performing sterilization process and storage, as it may affect the sterilization efficacy. Total weight of a complete instrument tray and sterile barrier system should not exceed 25lb (11.4kg).

Single Use Instruments:

18. Single use instruments must not be reused and must be discarded after the completion of a surgical procedure.

19. Reuse of single use instruments may pose health and/or safety risks to the patient and surgeon that may include, and are not limited to cross-infection, breakage resulting in irretrievable fragments, compromised mechanical performance due to wear, loss of function and effectiveness of proper cleaning and sterilization.

20. Attention should be paid to instruments performing drilling, sawing, cutting and boring functions (e.g. drills, wires, saw blades, reamers). Inspect cutting feature prior to use and do not use if damaged or worn which could adversely affect safety, performance and/or compliance with relevant specification.

Reusable Instruments:

21. Reusable instruments have a limited lifespan. Considerations for reusability relate to maintenance of device function and physical integrity. Generally, end of life is determined by wear, damage and compromised performance due to use. Inspect instruments for damage or malfunction prior to each use and at all stages of handling.

22. Prior to and after each use, reusable instruments must be inspected where applicable for sharpness, wear, damage, proper cleaning, corrosion and physical integrity of mechanical functions. If instrument appears damaged, it should not be used.

23. Attention should be paid to instruments that perform driving/fastening, clamping, inserting/extracting/retracting and gauging functions (e.g. drivers, bone clamps, depth gauges).

24. Some TriMed driver shafts must be connected to a hand-held, manually operated handle, and are not advised to be placed under power equipment. Possible risks using drivers under power include stripping, bending, cracking or fracturing of the instrument and/or implant. For driver shafts where power equipment may be used, the surgeon must carefully control of the speed and power of insertion. It is inappropriate to use power equipment with smaller sizes of TriMed driver shafts and some cannulated drivers. It is the responsibility of the surgeon to ensure safe use.

Point of Use Care:
TriMed products that have become soiled or contaminated should be manually processed during the surgical procedure prior to cleaning and sterilization.

1. Throughout the surgical procedure, blood and/or debris should be continuously wiped with a disposable gauge pad or cloth to prevent adhesion from drying onto the device's surface.
2. Cannulas of soiled, cannulated devices should be flushed with sterile or distilled water.
3. To avoid contamination, soiled devices should be contained and transported separately from non-contaminated devices.
4. To further prevent soils from drying on device surfaces, a towel moistened with sterile or distilled water should be draped over the instruments.

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: The first and most important step in decontaminating all re-usable instruments and instrument trays is thorough cleaning and rinsing. Through cleaning is a complex process whose success depends on various interrelated factors: water quality, quantity and type of cleaning agent, cleaning method, thorough rinsing and drying, proper product preparation, time, temperature, and thoroughness of the individual responsible for cleaning. Residual organic matter and/or large number of microorganisms may reduce the effectiveness of the sterilization process.

For non-sterile, reusable instruments and trays, TriMed recommends cleaning devices in a timely manner subsequent to point of use, using 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.

Doc. No.: LC-73-0004-014 Rev. D (Nov-19)

Note: Trained personnel must perform cleaning and mechanical inspection prior to sterilization.

5. 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. Note: Soiled trays must be stripped of its clean, unused devices.

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

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

8. 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).

9. 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, visually inspect that the debris is removed from the instrument. If debris remains, use a syringe to flush the device or repeat rinsing until debris is removed.

10. Prepare a newly-made enzymatic cleaning solution Steris® Prolystica® 2X Concentrate Enzymatic Presoak according to the manufacturer's instructions. Place all instruments within a container with the enzymatic cleaning solution and place the container in the sonication unit. Note: Instrument trays should be placed in appropriate size sonication unit.

11. 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.

12. 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.

13. Repeat steps 11 and 12 with freshly prepared cleaning solution if there is a sign of blood or soil in the tap water bath.

14. Remove the device 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, visually inspect that the debris is removed from the device. If debris remains, use a syringe to flush the device or repeat rinsing until debris is removed.

15. 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. If soil, remains, repeat the aforementioned cleaning process. Note: Thorough drying of instruments prevents corrosion from mineral content, condensate and residual agents.

Warning: Use of automated washer/dryer systems absence manual cleaning is not recommended as the sole cleaning method for TriMed Surgical Instruments and instrument trays.

Inspection, Assembly and Maintenance: After cleaning, TriMed Surgical Instruments and instrument trays are to be inspected for damage, wear, contamination and malfunctioning parts. In case of visible residues, instruments must be cleaned again.

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

2. Multi-component instruments have to be re-assembled.

3. Instrument oil, suitable for autoclaving and successfully tested for biocompatibility, can be used to service actuating parts.

4. Final inspection can comprise of, but not limited to,
    a. Visual intactness
    b. Completeness of multi-component instruments
    c. Operability of actuating parts
    d. Proper function

Sterilization: TriMed recommends the following sterilization procedures for non-sterile, instruments and instrument trays. 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. Note: Do not stack trays when applying sterilization wrap and when performing the sterilization process, as it may affect the sterilization efficacy.

4. Wrap the instrument tray with appropriate 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

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®

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

For a complete list of patents, visit: trimedortho.com/patents

Doc. No.: LC-73-0004-014 Rev. D (Nov-19)