INSTRUCTIONS FOR USE
TriMed® Nitinol Staple System

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

General:
The TriMed® Nitinol Staple System is an aid to the treatment of fractures, osteotomies, or arthrodesis. Like all orthopaedic implants, they cannot be assumed to be uniformly effective without risk as they are not a substitute for normal tissue healing. Therefore, the TriMed Nitinol Staple is designed to provide additional constraint of movement of a bone and is intended only as an aid for fixation during the healing process.

Basic Design Features:
The TriMed Nitinol Staple System consists of a variety of staples and accompanying instrumentation. The staples are sterile, non-bioabsorbable, implantable devices designed to address common types of deformity corrections, fusions, fractures and osteotomies in extremities amenable to staple fixation all depending on the size, shape, and location of the fractured bone and bone fracture fragments. Staples are manufactured from implantable Nitinol.

Indications, Contraindications, Adverse Effects:
Patient selection and sound surgical principles apply to the use of the TriMed Nitinol Staples 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 Indications:
The TriMed Nitinol Staple System is intended for use in fractures, osteotomy, and arthrodesis of the following areas of the body: small bones in the hand and foot.

Contraindications:
1. Physical conditions that would eliminate or tend to eliminate adequate implant support or retard healing, viz.: osteopenia, 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 performed prior to material selection or implantation. In particular, the physician should be aware that the TriMed Staple is made from a material containing nickel. Therefore, the physician should use sound medical judgment if a nickel allergy or hypersensitivity is suspected. Note: See material composition under general regulatory information section.
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 internal fixation 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. Infections, both deep and superficial.
5. Tissue reactions as the result of allergy or foreign body reaction.
6. Pain, a feeling of malaise, or abnormal sensations due to the implant used.
7. Hematoma.
8. Stiffness of the adjacent joint with or without degenerative changes.
9. Tendinitis or tendon rupture.
10. Scarring.
11. Reflex sympathetic dystrophy.
12. Local bursitis and pain from prominent hardware.

The adverse effects listed here are not specific to TriMed Nitinol Staples but 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 explant(s) in a cleaned, disinfected and sterile condition. TriMed cannot accept any other returns of used implants.

Warnings and Precautions
1. Pre-operative and operating procedures, including knowledge of surgical techniques and proper selection of the device, are important considerations in the successful utilization of this device.
2. Use caution in the handling and storage of implants. Cutting, bending, or scratching the surface of the implant is strictly forbidden. Implants should be stored away from corrosive agents and environments. If implants appear damaged, they should not be implanted.
3. Implantation in patients with the contraindications specified previously should be avoided. 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.
4. Patients who are allergic to nickel may have an allergic reaction to this device, especially those with a history of metal allergies. Some patients may develop an allergy to nickel if this device is implanted.
5. A full inventory of instruments and implants should be available prior to initiation of the surgical procedure.

6. The surgeon should be fully familiar with the biomechanics and surgical principles inherent to the use of this device (see Surgical Technique, LC-72-0001-001). Improper selection, placement or positioning may result in reduced lifetime of the implant(s).
7. Do not use other manufacturer's instruments or implants in conjunction with TriMed Nitinol Staples. Failure to use the provided, unique instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
8. TriMed has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.
9. As with other orthopaedic implants used in this capacity, the surgeon should take measures to avoid excessive force on the implant 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.
10. 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 regimen prescribed by the physician should be strictly followed to avoid adverse stresses applied to the device (e.g., casting, splints).
11. Reduction of the site should be achieved and maintained prior to implanting the staple. The compressive force of the staple closing should not be relied upon to achieve closure or reduction of a fracture line.
12. Staples should be adequately secured into bone in order to ensure strong fixation. Do not over compress the staple as this can cause bone deformation and result in reduced pull-out resistance. Do not over distract (i.e., past parallel) as it may potentially lead to premature staple fatigue, loss of performance, or breakage in situ.
13. Any adjacent soft tissue structures should be checked to ensure that abrasive rubbing against components will not occur.
14. Size and position of components should be checked radiographically prior to completion of the surgical procedure.
15. These devices are intended for single use only. Violation of this warning could potentially result in loss of performance, function, fit or device failure, and could potentially result in infection or failure.
16. 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.
17. This product is sold STERILE. It is sterilized by gamma irradiation at a minimum dose of 25 kGy (in compliance with ISO 11137). Do not re-sterilize. Do not use implants after use-by date.
18. The implant must always be handled in accordance with Good Clinical Practice.

Packaging and Labeling for Staple:
1. Staples are provided pre-sterilized in a single-use package.
2. Confirm the integrity of the packaging (external packaging and double internal packaging) and the use-by date stated on the label on the outside of the box before use.
3. Do not use if the package is damaged, integrity is suspect, or has exceeded the use-by date.
4. Contact Customer Service if the package has been opened or altered.

Storage Conditions:
TriMed Nitinol Staples must be stored in the original unopened packaging, away from moisture and should not be used after the use-by date. The instrumentation should be stored in a clean, dry environment. Also, the oldest staple lots must be used first.

Recommendations for Instrument Cleaning and Sterilization:
Reference TriMed Instruments Instruction for Use (See IFU, LC-73-0004-014).

General Regulatory Information

Material composition for Wrought Nickel-titanium Shape Memory medical grade implant alloy: Nickel (54.5-57.0%), Carbon (0.050%), Cobalt (.050%), Copper (0.010%), Chromium (0.010%), Hydrogen (0.005%), Iron (0.050%), Niobium (0.025%), Nitrogen plus Oxygen (0.050%), Titanium (balance).

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

Symbol	Symbol Description	Symbol	Symbol Description
REF	Catalog Number		Single Use Only. Do Not Re-use.
LOT	Lot Number	STERILE R	Sterilized Using Irradiation
	Date of Manufacture		Do Not Use If Package Is Damaged
	Manufacturer		Consult Instructions for Use
	Use-by-date		Caution
	Do Not Re-sterilize	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

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