Sniper Staple System, Non-Sterile
Instructions for Use

900-01-017 Rev D
April 2023

Description
The Non-Sterile Sniper Staple System is comprised of Nitinol staples designed for fixation of fractures and osteotomies. The Sniper Staple System includes staple implants with bridge sizes 8-25mm. Available staples and instrumentation will be packaged as a single system. The system instruments include staple spreaders, drill guides, drill bits, locating pins, and a tamp to facilitate the placement of the staples. The implants and drill bits are intended for single use only. All other system components are intended for reuse.

Implant Materials
All Sniper Staple System staples are made from Nitinol (ASTM F-2063). The instrumentation is made from stainless steel.

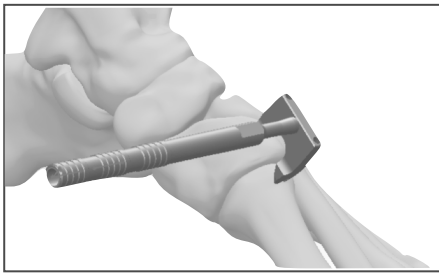
Indications
The Trilliant Sniper Staple System is indicated for fixation of fractures and osteotomies of the hand, foot, and bones appropriate for the size of the device.

Contraindications
Use of the Sniper Staple System is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to nickel or titanium; or in patients with certain metabolic diseases. It is further contraindicated in patients exhibiting disorders, which would cause the patient to ignore the limitations of internal fixation.

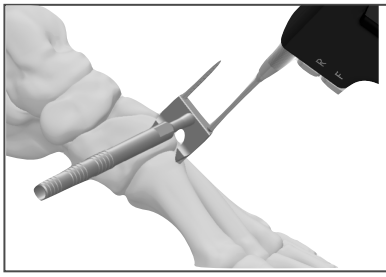
Warnings
1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
3. Plates, screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
4. Instruments and implants are to be treated as sharps.
5. Reuse of devices indicated as single use can result in decreased mechanical and clinical performance of devices.

Maintaining Device Effectiveness
1. The surgeon should have specific training, experience, and thorough familiarity with the use of staple fixation systems.
2. The surgeon must exercise reasonable judgment when deciding which staple to use for specific indications.
3. The staples in the Sniper Staple System are not intended to endure excessive abnormal functional stresses.
4. The Sniper Staple System is intended for temporary fixation only until osteogenesis occurs.
5. All Sniper Staple System implants and instrumentation may be required for each surgery. Failure to use dedicated, unique Trilliant Surgical 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.
6. Carefully inspect the staples prior to use, inspect the instruments before and after each procedure to assure they are in proper operation condition. Instruments which are faulty, damaged or suspect should not be used.
7. Trilliant Surgical recommends the use of Trilliant Surgical products in a sterile environment.

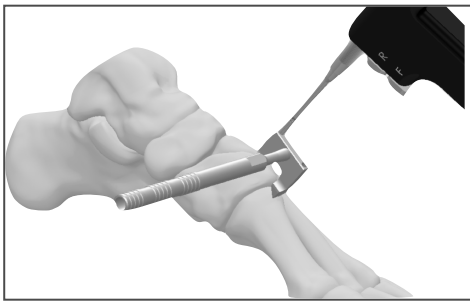
Instructions for Use, Sniper Staple System



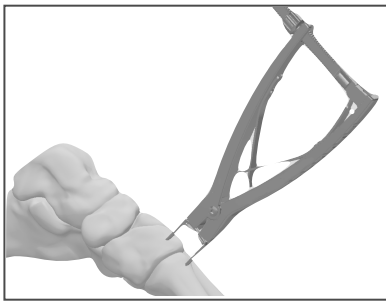
1. Place a bone clamp to create the necessary compression across the osteotomy, fracture or fusion site.
2. Place desired drill guide across the osteotomy, fracture or fusion site.



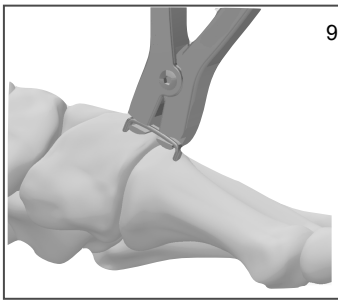
4. Pivot drill guide, if necessary.
5. Drill the second hole in the bone by inserting the pilot drill into the adjacent drill guide hole.



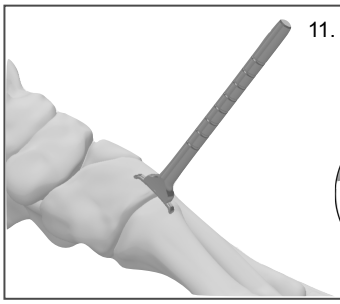
3. Drill the first hole to the correct depth in the bone using the appropriate sized pilot drill. Toggle the proximal shaft of the snap-off pilot drill to remove the drill shaft and create a post. Insert supplied locating pin, if desired.



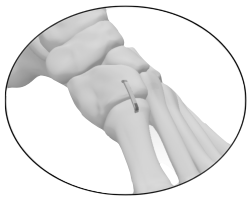
6. Remove the drill guide and locating pin.
7. Select the staple with bridge width corresponding to the drill guide used.
8. Use the appropriate staple spreader to spread the staple apart to a parallel leg position. Maintain the staple position by using the locking nut on the staple spreader.

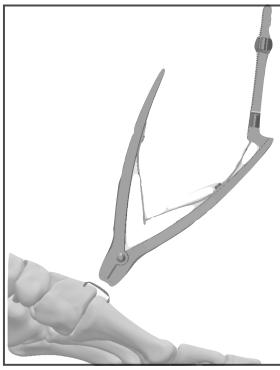


9. Insert the staple legs into the pre-drilled pilot holes until the dispenser abuts the osteotomy or fusion site.



11. Using the tamp, push on the staple bridge until final, flush staple placement is achieved.





10. Release locking nut mechanism on the staple spreader to release the staple and compress the osteotomy.

Staple Removal (If necessary)

1. Locate staple with intra-operative imaging.
2. Palpate the staple and remove surrounding soft tissue to gain maximum exposure.
3. Use forceps or pliers to remove by pulling on the staple bridge.

Cleaning

Trained personnel must perform cleaning and mechanical inspection prior to sterilization. Compliance is required with the equipment manufacturer's user instructions (manual and/or machine cleaning, ultrasound treatment, etc.) and recommendations for chemical detergents. Trays shall be thoroughly cleaned and visually inspected to ensure cleanliness. Repeat cleaning if visual inspection shows any contaminants or debris. For cleaning instructions, please reference Sniper Staple System Cleaning and Sterilization Protocol, 900-06-019.

Packaging and Sterility

NON-STERILE PRODUCT

The Sniper Staple System (Instruments and implants) can be packaged non-sterile and therefore must be sterilized prior to surgical use. Use of the sterilizer shall comply with the manufacturer's user instructions. The user facility must clean and disinfect instruments prior to sterilization per standard hospital procedures. Non-sterile devices are sterilizable by steam sterilization (autoclaving). The following parameters should be followed:

Sterilization Method	Pre-Vacuum Steam
Condition	Wrapped*
Temperature	270°F (132°C)
Time	4 minutes
Dry Time	Recommended 70 minutes**

* The system shall be packaged for sterilization by double wrapping in an FDA- cleared wrap (i.e. Bio-Shield® Sterilization Wrap).
** Trilliant Surgical has validated the recommended sterilization cycle and dry time for trays. The dry time varies due to load configuration, wrapping method, and material.

CAUTION

Federal Law (USA) restricts this device to sale by or on the order of a physician. Do not attempt a surgical procedure with faulty, damaged or suspect Trilliant Surgical instruments or implants. Inspect all components preoperatively to assure utility. Do not use the Sniper Staple Sterilization Tray to sterilize, clean, or transport any components that are not associated with the Sniper Staple System. Do not stack trays during sterilization.

MRI Safety Information

The Sniper Staple System 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 the Sniper Staple System implants in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Symbols Glossary

Symbol	Description	Designation Number, ISO 15223-1:2021
REF	Catalog Number	5.1.6
LOT	Batch Code	5.1.5
	Do not use if package is damaged	5.2.8
	Do not reuse	5.4.2
NON STERILE	Non-Sterile	5.2.7
Rx only	Device only to be sold on or by the order of a physician	N/A*
	Manufacturer	5.1.1
	Caution	5.4.4
	Consult instructions for use	5.4.3

*Symbol allowed under 21 CFR 801. The above symbols are outlined in ISO 15223-1:2021 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements. Note: QTY is an abbreviation of "QUANTITY".

Please contact company for product inquiries and surgical techniques, or to report any adverse experience.

Trilliant Surgical
727 North Shepherd Drive | Suite 100 | Houston, TX 77007
1-800-495-2919 | trilliantsurgical.com