

### Description

The Sniper Staple System is comprised of staples and instrumentation used for management of osteotomies, reconstruction, and trauma of the bones of the hand and foot. System instrumentation includes a drill guide, pilot drills, and a deployment device to facilitate the placement of the staple. The Sniper Staple System is intended for single use only.

### Implant Materials

All staples are made from Nickel-Titanium Alloy (Nitinol). The instrumentation is made from medical grade stainless steel.

### Indications

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




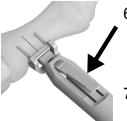

### Warnings

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 staple 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, guides, and staples are to be treated as sharps.
5. Re-use of devices indicated as single use can result in decreased mechanical and clinical performance of devices.



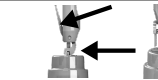
### Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of staple fixation.
2. The surgeon must exercise reasonable judgment when deciding which staple size to use for specific indications.
3. The staples are not intended to endure excessive abnormal functional stresses.
4. The staples are 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 staple and instrumentation prior to use to ensure they are in proper operating condition.
7. The Sniper Staple System should be used in a sterile environment.

### Instructions for Use, Sniper Staple System

 <ol style="list-style-type: none"> <li>1. Place a bone clamp to create the necessary compression across the osteotomy, fracture, or fusion site (when applicable).</li> <li>2. Place drill guide in desired position across the osteotomy, fracture or fusion site.</li> </ol>	 <ol style="list-style-type: none"> <li>4. Pivot position of the drill guide if desired.</li> <li>5. Drill second hole using additional snap-off drill post provided.</li> </ol>
 <ol style="list-style-type: none"> <li>3. Using a wire pin driver, drill the first hole in the bone using the snap-off drill post provided. Toggle the proximal shaft of the snap-off drill post to remove the drill shaft and create a post.</li> </ol>	 <ol style="list-style-type: none"> <li>6. Remove drill guide and post. Insert staple legs into pre-drilled holes until the distal tip of the deployment device abuts the bone.</li> <li>7. Press trigger to deploy the staple.</li> </ol>
 <ol style="list-style-type: none"> <li>8. Fully seat the staple.</li> <li>9. OPTIONAL: The distal section of the deployment device may be utilized as an impactor to fully seat the staple if deemed necessary by the surgeon.</li> </ol>	

### Staple reloading (if necessary):

 <ol style="list-style-type: none"> <li>1. Insert staple legs into the applicable holes in the applicable holes in the safety cap.</li> <li>2. Press firmly until staple is fully seated and legs are in parallel orientation.</li> </ol>	 <ol style="list-style-type: none"> <li>3. Press trigger to open deployment device and align staple bridge over distal groove of the dispenser.</li> </ol>	 <ol style="list-style-type: none"> <li>4. Release the trigger and push barrel forward to reload the staple.</li> <li>5. Remove staple from the safety cap.</li> </ol>
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### Packaging and Sterility

Trilliant Surgical Sniper Staple System is supplied sterile (Gamma Sterilized). In accordance with ISO 11137:2006, two methods of sterilization are allowed. Both provide a sterility assurance level (SAL) of 10<sup>-6</sup>. These are "Method 1" and "VDmax". Prior to use, inspect package for damage, which may compromise sterility. If damaged, the product must be assumed to be non-sterile.

### DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.










Surgical implants should not be reused. Any implant once used should be discarded. Even though it may appear undamaged, it may have small defects or internal stress patterns, which may lead to failure.

### 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.

### 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 Sniper Staple System 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 15223-1:2016
	Catalog Number	5.1.5
	Batch Code	5.1.6
	Do not use if package is damaged	5.2.8
	Do not reuse	5.4.2
	Use-by date	5.1.4
	Sterilized using irradiation	5.2.4
	Device only to be sold on or by the order of a physician	N/A*
	Manufacturer	5.1.1
	Consult instructions for use	5.4.3

\*Symbol allowed under 21 CFR 801. The above symbols are outlined in ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements.

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

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