

# INSTRUCTIONS FOR USE

## 4.5mm Tiger Cannulated Screw System

### Description

The 4.5mm Tiger Cannulated Screw System is comprised of screws used for bone fixation of the hand and foot following trauma or osteotomy. The Tiger Screw is a cannulated, threaded bone screw which is offered in 4.5mm diameter with lengths of 20-70mm. System instrumentation includes drill bits, drill sleeves, guide wires, depth gauge, countersink, screw removal tools, driver shafts and handles to facilitate the placement of the screws. The drill bits, screws, washers and guide wires are intended for single use only. All other system components are intended for reuse.

### Implant Materials

All 4.5mm Tiger Cannulated Screws and washers are made from Titanium Alloy (ASTM F-136). The instrumentation is made from medical grades of titanium, stainless steel, anodized aluminum, and plastic.

### Indications

The 4.5mm Tiger Cannulated Screw System is indicated for fixation of fractures, non-unions, arthrodeses, and osteotomies of bones appropriate for the size of the device.

### Contraindications

Use of the 4.5mm Tiger Cannulated Screw System is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to 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 screw in areas of high functional stresses may lead to implant fracture and failure.
3. Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
4. Instruments, guide wires and screws 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 cannulated screws.
2. The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
3. The 4.5mm Tiger Cannulated Screws are not intended to endure excessive abnormal functional stresses.
4. The 4.5mm Tiger Cannulated Screws are intended for temporary fixation only until osteogenesis occurs.
5. All 4.5mm Tiger Cannulated Screw 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 screws prior to use, inspect the instruments before and after each procedure to ensure they are in proper operating condition. Instruments which are faulty, damaged or suspect should not be used.
7. The 4.5mm Tiger Cannulated Screw System should be used in a sterile environment.

### Instructions for Use, 4.5mm Tiger Cannulated Screws

1. Place a bone clamp to create the necessary compression across the osteotomy or fusion site (when applicable). **Note:** This step is very important if bone is very dense and in arthrodesis, as the axial force necessary for inserting the Tiger Cannulated Screw could temporarily distract the fragments at the fracture/arthrodesis line.



2. Insert appropriately sized K-wire to the correct length under image intensification. Avoid bending the K-wire when placing into bone by inserting in 15mm - 20mm increments.



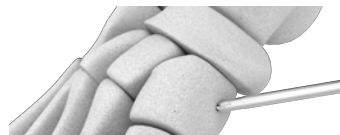
3. Slide the appropriately sized depth gauge over the guide wire until the tip contacts bone. Measure for the desired screw length by examining the end of the K-wire in relation to the marks on the depth gauge.

#### For Headed Screws



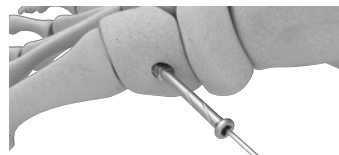
4. Slide the appropriately sized countersink over the guide wire until the countersink tip contacts bone. Rotate the countersink clockwise and counterclockwise to create the necessary recess in the bone.

#### For Headless Screws

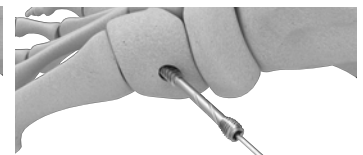


4. Pre-drill the proximal cortex with the appropriately sized proximal drill to provide proper clearance for screw head placement.

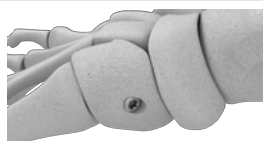
#### Headed Screw



#### Headless Screw



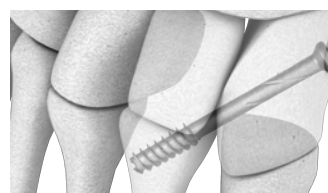
5. It is recommended to pre-drill in cases of dense bone, when using a screw over 24mm, or when passing through three or more cortices.
6. When using a fully threaded screw, overdrilling is required to achieve compression.
7. Remove the desired 4.5mm Tiger cannulated screw from the screw block. Slide the screw over the K-wire.



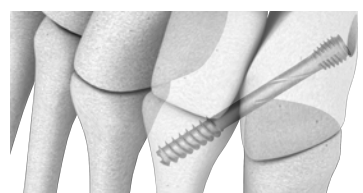
8. Using the screw driver and appropriate driver shaft, drive the 4.5mm Tiger Cannulated Screw into bone rotating clockwise until desired compression is achieved.

9. Remove and discard the K-wire.

#### Headed Screw



#### Headless Screw



**Screw Removal (if necessary)**

1. Locate the implant with intra-operative imaging.
2. Palpate the head of the screw and remove surrounding soft tissue to gain maximum exposure.
3. Engage the screw head with appropriate driver and rotate counterclockwise until screw is removed. *Note: Solid core driver is included for this purpose.*
4. OPTIONAL: If the screw head is stripped, engage the proximal shaft under the screw head with the screw removal tool and continue turning counterclockwise while exerting light pressure upwards with the removal tool.
5. If the screw is integrated into bone, core out with trephine drill.
6. Once the screw is removed it should be treated as medical waste and disposed of accordingly.

**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. For validated cleaning instructions, please reference document 900-06-022, 4.5mm Tiger Cannulated Screw System Cleaning and Sterilization Proto-col.

**Packaging and Sterility**

**NON-STERILE PRODUCT**

The 4.5mm Tiger Cannulated Screw System (instruments and implants) can be packaged non-sterile and therefore must be sterilized prior to sur-gical use. Use of the sterilizer shall comply with the manufacturer’s user instructions. The user facility must thoroughly clean and disinfect instru-ments prior to sterilization per standard hospital procedures. Non-sterile devices are sterilizable by steam sterilization (autoclaving). The following parameters should be followed:

<b>Sterilization Method</b>	Pre-Vacuum Steam
<b>Condition</b>	Wrapped*
<b>Temperature</b>	270°F (132°C)
<b>Time</b>	4 minutes
<b>Recommended Dry Time</b>	30 minutes**

\* The system shall be packaged for sterilization by double wrapping in an FDA cleared wrap (i.e. Halyard® Sterilization Wrap) and wrapping techniques outlined per ANSI/AAMI ST79, then adhered with FDA cleared chemical indicator autoclave tape.

\*\* 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.

Note: Do not stack trays during sterilization.

**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 Tril- liant Surgical instruments or implants.

Inspect all components preoperatively to assure utility.

**MRI Safety Information**

The 4.5mm Tiger Cannulated Screw 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 4.5mm Tiger Cannulated Screw System in the MR environment is un- known. Scanning a patient who has this device may result in patient injury.

<b>Symbols Glossary</b>		
<b>Symbol</b>	<b>Description</b>	<b>Designation Number, ISO 15223-1:2021</b>
	Catalog Number	5.1.6
	Batch Code	5.1.5
	Do not use if package is dam- aged	5.2.8
	Do not reuse	5.4.2
	Non-Sterile	5.2.7
	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.**

**This document is controlled by Trilliant Surgical. When downloaded, printed, and/or copied, this document becomes UNCONTROLLED and users should always check Trilliant Surgical’s website, www.trilliantsurgical.com, to ensure they have the latest version.**

