

Tiger Headless Cannulated Screw System

Instructions for Use

900-01-004 Rev B

Description

The Tiger Headless Cannulated Screw Fixation System is comprised of screws used for bone fixation of the hand and foot following trauma or an osteotomy. The Tiger Headless Screw is a cannulated, threaded bone screw which is offered in 2.0, 2.4, & 3.0 diameters with lengths of 10 - 34mm. Available screws and instrumentation can be packaged as a single system or the screws may be offered in a single sterile packaged offering. The system instruments include drill bits, guide wires, depth gauges, bone clamps, screw removal tools, and screwdrivers to facilitate the placement of the screws.

Implant Materials

All Tiger Headless Cannulated Screws 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 Tiger Headless Cannulated Screw Fixation System implants (screws) are intended for fixation of fractures, non-unions, arthrodeses and osteotomies of the small bones in the hand and foot. The implants, drills, and guide wires are intended for single use only.

Contraindications

Use of the Tiger Headless Cannulated Screw Fixation 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

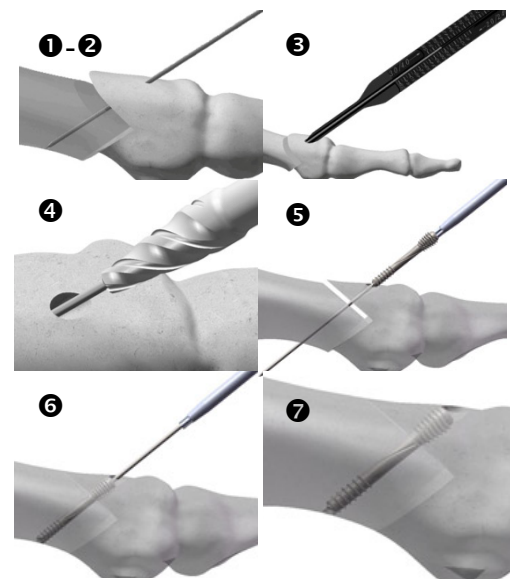
1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
3. Plates and screws, 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.

Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of headless cannulated screws.
2. The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
3. The Tiger Headless Cannulated Screws are not intended to endure excessive abnormal functional stresses.
4. The Tiger Headless Cannulated Screws are intended for temporary fixation only until osteogenesis occurs.
5. All Tiger Headless Cannulated Screw Fixation 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 assure they are in proper operating 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, Headless 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 arthrodeses, as the axial force necessary for inserting the Tiger Headless Cannulated Screw could temporarily distract the fragments at the fracture/arthrodeses line.
2. Insert the appropriately sized guide wire to the correct length under image intensification. Please avoid bending the K-wire when placing into bone. To avoid bending the guide wire, insert the wire in 15mm - 20mm increments.
3. Measure for the desired screw length by examining the end of the guide wire in relation to the marks on the depth gauge.
4. It is recommended to pre-drill the proximal cortex with the appropriately sized proximal drill to prevent the threaded screw head from cracking the cortex. For any screw over 24mm in length, no matter the diameter, pilot drilling with a standard cannulated drill is recommended.
5. Remove the desired headless cannulated screw from the screw block. Slide the headless screw over the guide wire.
6. Using the screw driver and appropriate driver shaft, drive the Tiger Headless Cannulated Screw into bone until the desired compression is achieved.
7. Remove and discard the guide wire.



Screw Removal (If necessary)

1. Locate implant with intra-operative imaging.
2. Palpate head of screw and remove surrounding soft tissue to gain maximum exposure.
3. Engage screw head with appropriate driver and rotate counterclockwise until screw is removed.
4. OPTION: If screw head is stripped, engage proximal shaft of screw under screw head with screw removal tool and continue turning counterclockwise while exerting light pressure upwards with the removal tool.
5. If screw is integrated into bone, core out with trephine drill.

Cleaning

Non-sterile products must be carefully cleaned prior to sterilization. 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. Trilliant Surgical recommends the following cleaning and sterilization instructions for Instrumentation:

1. Clean all instruments thoroughly using mild detergent, soft brush and warm water. Ensure that dried blood, bone particulate and other deposits are removed from the instruments and sterilization tray.
2. Thoroughly rinse all instruments and the sterilization tray with clean water.
3. Arrange all the instruments in the sterilization tray and insure that the lid is in place and properly closed.
4. Steam autoclave per the following sterilization instructions.

Packaging and Sterility**NON-STERILE PRODUCT**

The Tiger Headless Cannulated Screw Fixation 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.

Pre-Vacuum Steam Sterilization:	Gravity Steam Sterilization:
Condition: Wrapped	Condition: Wrapped
Temperature: 270· F (132· C)	Temperature: 270· F (132· C)
Time: 15 minutes	Time: 40 minutes
Recommended 20-30 minute dry time*	Recommended 15-30 minute dry time*

*Recommended dry times per AAMI ST79

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.

Trilliant Surgical Ltd
602 Sawyer Street, Suite 120
Houston, TX 77007 1-800-495-2919

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

