

Tiger Headless Cannulated Screw System Instructions for Use

Description

The Tiger Headless Cannulated Screw Fixation System is comprised of screws used for bone fixation of the hand and foot following trauma or 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. System instrumentation includes drill bits, guide wires, depth gauges, screw removal tools, and driver shafts and handles to facilitate the placement of the screws. The implants, drill bits, and guide wires are intended for single use only. All other system components are intended for reuse.

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 Screws are intended for fixation of fractures, non-unions, arthrodeses and osteotomies of the small bones in the hand and foot.

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

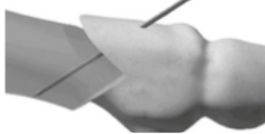
1. Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
2. Use of an undersized screw in areas of high functional stresses may lead to implant fracture and failure.
3. Plates and screws, 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.
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 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 ensure they are in proper operating condition. Instruments which are faulty, damaged or suspect should not be used.
7. The Tiger Headless Cannulated Screw System should be used in a

Instructions for Use, Headless Cannulated Screws

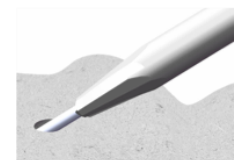
1. Place a bone clamp to create the necessary compression across the osteotomy or fusion site (when applicable). **Note:** This step is very important if bone is very dense and in arthrodesis, as the axial force necessary for inserting the Tiger Headless Cannulated Screw could temporarily distract the 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. Measure for the desired screw length by examining the end of the K-wire in relation to the marks on the depth gauge.



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



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. Remove the desired Tiger Headless Cannulated Screw from the screw block. Slide the headless screw over the guide wire.



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



8. Remove and discard the K-wire.

Screw Removal (if necessary)

1. Locate the implant with intra-operative imaging.
2. Locate the head of the screw and remove surrounding soft tissue to gain maximum exposure.
3. Engage the screw head with the appropriate driver and rotate counterclockwise until screw is removed.
4. OPTION: If 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 900-06-007, Tiger Cannulated and Tiger Headless Cleaning and Sterilization Protocol.

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:

Sterilization Method	Pre-Vacuum Steam	Gravity Steam
Condition	Wrapped*	Wrapped*
Temperature	270°F (132°C)	270°F (132°C)
Time	4 minutes	40 minutes
Dry Time	Recommended 50 minutes**	Recommended 50 minutes**

* The system shall be packaged for sterilization by double wrapping in standard central supply 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.

MRI Safety Information

The Tiger Headless 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 Tiger Headless Cannulated Screw 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 15223-1:2021
	Catalog Number	5.1.6
	Batch Code	5.1.5
	Do not use if package is damaged	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.

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