

Tiger Large Cannulated Headless Screw System

Instructions for Use

Description

The Tiger Large Cannulated Headless Screw Fixation System is comprised of screws used for bone fixation of the hand and foot following trauma or osteotomy. The Tiger Large Cannulated Headless Screw is a cannulated, threaded bone screw, which is offered in sizes 5.5mm - 7.0mm in diameter and 30mm - 120mm in length with both long thread and short thread options. 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, proximal drills, guide wires, a depth gauge, drill sleeves, guide wire sleeves, screw sleeves, trocars, parallel wire guides, a screw extractor, driver shafts and handles to facilitate the placement of the screws. The implants, drill bits, and guide wires are intended for single use only. The other system components are intended for reuse.

Implant Materials

All Tiger Large Cannulated Headless screws are made from Titanium Alloy (ASTM F-136). The instrumentation is made from medical grades of 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 Large Cannulated Headless 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.


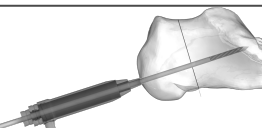
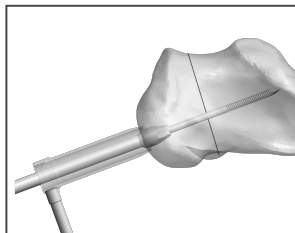
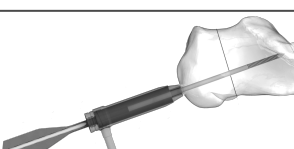
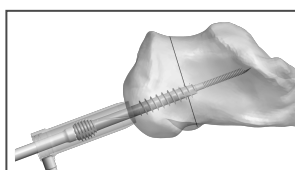


Warnings

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.

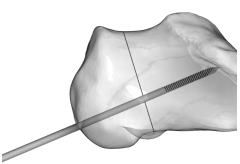
Maintaining Device Effectiveness

1. The surgeon should have specific training, experience, and thorough familiarity with the use of cannulated screws.
2. The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
3. The Tiger Large Cannulated Headless Screws are not intended to endure excessive abnormal functional stresses.
4. The Tiger Large Cannulated Headless Screws are intended for temporary fixation only until osteogenesis occurs.
5. All Tiger Large Cannulated Headless 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 Large Cannulated Headless Screw System should be used in a sterile environment.

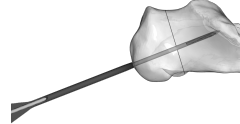
Instructions for Use, Large Cannulated Screws with Sleeve Assembly

	<ol style="list-style-type: none">1. If distraction of osteotomy or fracture site occurs or is likely, a bone clamp may be used to help mitigate displacement.2. If use of the sleeve assembly is desired, assemble using a fixed handle and by inserting the appropriate size sleeves per desired implant diameter used in the following order: screw sleeve, drill sleeve, guide wire sleeve, and trocar.
 <ol style="list-style-type: none">3. Apply sleeve assembly to surgical site. If necessary, use the trocar to clear excess tissue. Remove the trocar sleeve from the sleeve assembly.4. Using the guide wire sleeve, insert the appropriate size K-wire to the desired depth under image intensification. <p>Avoid bending the K-wire when placing into bone by inserting in 15mm – 20mm increments. Once K-wire is placed, remove the guide wire sleeve from the sleeve assembly.</p>	 <ol style="list-style-type: none">7. In cases of dense bone, place the proximal drill over the K-wire until the tip contacts bone. Drill until the indication line on the instrument aligns with the proximal end of the drill sleeve to provide proper clearance for screw head placement.8. Remove the desired Tiger Large Cannulated Headless Screw from the screw block. Slide the screw over the K-wire.
 <ol style="list-style-type: none">5. Slide the depth gauge over the K-wire advancing until the depth gauge 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.	 <ol style="list-style-type: none">9. Using a handle and the appropriate size driver shaft, drive the Tiger Large Cannulated Headless Screw into bone rotating clockwise until the desired fixation is achieved.
 <ol style="list-style-type: none">6. Pre-drill to reduce the axial force necessary for inserting the screw in cases of dense bone. Note: To avoid over drilling, drill in 5mm - 10mm increments. Remove the drill sleeve from the sleeve assembly.	 <ol style="list-style-type: none">10. Remove and discard the K-wire.

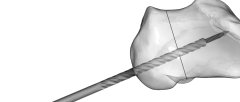
Instructions for use, Large Cannulated Headless Screws without Sleeve Assembly



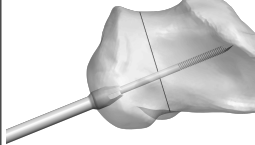
1. If distraction of osteotomy or fracture site occurs or is likely, a bone clamp may be used to help mitigate displacement.
2. If sleeve assembly is not utilized, ensure visibility and access to the site by retracting any ancillary soft tissue.
3. Insert the appropriate size K-wire to the desired depth under image intensification. Avoid bending the K-wire when placing into bone by inserting in 15mm – 20mm increments.



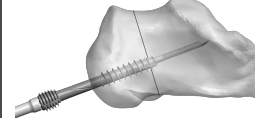
4. Slide the depth gauge over the K-wire advancing until the depth gauge contacts bone. Measure for the desired screw length by examining the end of the K-wire in relation to the marks on the depth gauge.




5. Pre-drill to reduce the axial force necessary for inserting the screw in cases of dense bone. **Note:** To avoid over drilling, drill in 5mm - 10mm increments.



6. In cases of dense bone, place the proximal drill over the K-wire until the tip contacts bone. Drill until the head tapers to the shaft diameter to provide proper clearance for screw head placement.
7. Remove the desired Tiger Large Cannulated Headless Screw from the screw block. Slide the screw over the K-wire.



8. Using a handle and the appropriate size driver shaft, drive the Tiger Large Cannulated screw into bone rotating clockwise until the desired fixation is achieved.



9. 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 screw head with appropriate driver. Rotate counterclockwise until screw is removed.
4. OPTION: If screw head is stripped, insert screw extractor into screw cannulation, tap with a mallet, and rotate counterclockwise until reverse threads are engaged. Continue rotating counterclockwise until screw is removed.
5. 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 900-06-012, Tiger Large Cannulated Headless Screw System Cleaning and Sterilization Protocol.

Packaging and Sterility

NON-STERILE PRODUCT

The Tiger Large Cannulated Headless 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	30 minutes
Dry Time	Recommended 50 minutes**	Recommended 70 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.

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

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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 Large Cannulated Headless 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 Large Cannulated Headless 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".

