Tiger Cannulated Screw System
Instructions for Use

900-01-002 Rev P
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Description
The Tiger Cannulated Screw Fixation 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 2.0, 2.4, 3.0 & 4.0mm diameters with lengths of 8 - 56mm. 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, drill guides, guide wires, depth gauges, countersinks, screw removal tools, driver shafts and handles to facilitate the placement of the screws. The implants and guide wires are intended for single use only.

Implant Materials
All Tiger 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 Cannulated Screw System is indicated for fixation of fractures, non-unions, arthrodeses, and osteotomies of bones appropriate for the size of the device.

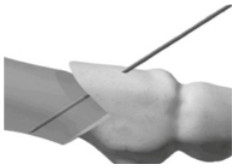
Contraindications
Use of the Tiger Cannulated Screw Fixation System is contraindicated in cases of active or suspected infection or in patients who are immunocompromised; in patients previously sensitized to titanium; or in patients with certain metabolic diseases. It is further contraindicated in patients 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.

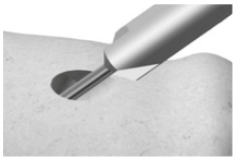
Maintaining Device Effectiveness
1. The surgeon should have specific training, experience, and thorough familiarity with the use of cannulated screws.
2. The surgeon must exercise reasonable judgment when deciding which screw type to use for specific indications.
3. The Tiger Cannulated Screws are not intended to endure excessive abnormal functional stresses.
4. The Tiger Cannulated Screws are intended for temporary fixation only until osteogenesis occurs.
5. All Tiger Cannulated Screw Fixation System implants and instrumentation may be required for each surgery. Failure to use dedicated, unique Trilliant Surgical Ltd. 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 Cannulated Screw System should be used in a sterile environment.

Instructions for Use, 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.

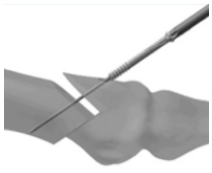


2. Insert appropriately sized K-wire to the correct length under image intensification. Avoid bending the K-wire when placing into bone by inserting in 15mm - 20mm increments.



3. Slide the appropriately sized depth gauge/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.

4. Measure for the desired screw length by examining the end of the K-wire in relation to the marks on the depth gauge.



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 cannulated screw from the screw block. Slide the screw over the K-wire.

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

8. Remove and discard the K-wire.

Instructions for Use, Tiger Cannulated Screws for Arthrodesis of the 2nd through 5th digits

1. Expose the joint space dorsal of the proximal interphalangeal joint.
2. Resect the articular surfaces of the proximal interphalangeal joint.
3. Using the wire pin driver and a 0.035" double trocar K-wire, insert the K-wire centrally into the middle phalanx, drilling towards the distal phalanx.
4. Position the distal phalanx in the desired position and continue inserting the K-wire, maintaining a central position.
5. Continue driving proximal to distal until the K-wire is protruding through the distal phalanx. Assure that the K-wire is sufficiently exposed to allow for capture with the wire pin driver.
6. With the wire pin driver, retract the K-wire until the proximal end is only exposed 1 to 2 mm.
7. Extend the digit to obtain proper alignment between the K-wire and the proximal phalanx. Surgeon judgement should be used to ensure sagittal plane stability and toe purchase.
8. Drive the K-wire to engage the proximal phalanx, assuring that the K-wire does not pass into the metatarsophalangeal joint.
9. CAUTION: Intra-operative imaging should be used to verify that the metatarsophalangeal joint space is not compromised by the K-wire. Verify that the wire is not bent in any way.
10. OPTIONAL: Countersink if desired and if bone surface is adequate.
11. Use the appropriate depth gauge to determine screw length.
12. Drill using the appropriate cannulated drill.
13. Place screw on K-wire and drive the screw until fully seated.
14. Remove the K-wire and discard.

Alternative Method for Arthrodesis of the 2nd through 5th digits.

- Use a 0.062" K-wire in place of the 0.035" K-wire.
- After step 9, replace the 0.062" K-wire with the 0.035" K-wire.
- Ensure that 0.035" K-wire follows pilot hole created by 0.062" K-wire
- Proceed with step 10, DO NOT DRILL AS STATED IN
- OPTIONAL STEP 12.

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.
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

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. For validated cleaning instructions, please reference document 900-06-007, Tiger Cannulated and Tiger Headless Cleaning and Sterilization Protocol.

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

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Packaging and Sterility

NON-STERILE PRODUCT

The Tiger 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 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 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 15223-1:2016
REF	Catalog Number	5.1.5
LOT	Batch Code	5.1.6
	Do not use if package is damaged	5.2.8
	Do not reuse	5.4.2
NON STERILE	Non-Sterile	5.2.7
Rx only	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 15223-1:2016 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".

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