HTR® Implant System
Instructions for Use

900-01-007 Rev K
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Description
The HTR System is comprised of Kirschner wires (K-wires) used for bone fixation of the hand and foot following trauma or osteotomy. The K-wire is offered in 0.045" to 0.062" diameters with a length of up to 6". System instrumentation includes reamers to facilitate the placement of the K-wires. The K-wires and reamers are intended for single use only.

Implant Materials
All K-wires are made from Stainless Steel (ASTM F138). The instrumentation is made from medical grade stainless steel.

Indications
The Trilliant Surgical K-wires are intended for use in fixation of bone fractures, for bone reconstructions, and as guide pins for insertion of other implants.

Warnings
1. Re-operation to remove or replace K-wires 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 K-wire in areas of high functional stresses may lead to implant fracture and failure.
3. Reamers and K-wires are to be treated as sharps.

Maintaining Device Effectiveness
1. The surgeon should have specific training, experience, and thorough familiarity with the use of K-wire fixation.
2. The surgeon must exercise reasonable judgment when deciding which K-wire type to use for specific indications.
3. The K-wires are not intended to endure excessive abnormal functional stresses.
4. The K-wires are intended for temporary fixation only until osteogenesis occurs.
5. All HTR® Implant 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 K-wires and reamers prior to use to ensure they are in proper operating condition.
7. The HTR® Implant System should be used in a sterile environment.

Instructions for Use, HTR® Implant System

1. Expose the joint space dorsal of the proximal interphalangeal joint.

2. Using a wire pin driver, resurface the head of the proximal phalanx with the concave reamer and the base of the middle phalanx with the convex reamer until the desired correction is achieved. Make sure to initiate the reamers down the center axis of the joint.

3. Using a wire pin driver and an appropriately sized K-wire, insert the K-wire centrally into the middle phalanx, drilling toward the distal phalanx.

4. Position the distal phalanx in the desired position and continue inserting the K-wire, maintaining a central position. 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.
5. With the wire pin driver, retract the K-wire until the proximal end is only exposed 1 - 2mm.
6. 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.

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 900-06-016, HTR® Hammer Toe Implant System and Two-Step Hammer Toe Implant System Cleaning and Sterilization Protocol.

Packaging and Sterility
NON-STERILE PRODUCT
The Trilliant Surgical HTR® Implant 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	15 minutes
Dry Time	Recommended 40 minutes**	Recommended 40 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.

STERILE PRODUCT
Trilliant Surgical HTR Systems can be supplied sterile (Gamma Sterilized). In accordance with ISO 11137:2006, two methods of sterilization are allowed. Both provide a sterility assurance level (SAL) of 10^{-6}. These are "Method 1" and "VDmax". Prior to use, inspect package for damage, which may compromise sterility. If damaged, the product must be assumed to be non-sterile.

DO NOT USE IF STERILE PACKAGE IS DAMAGED. DO NOT USE AFTER EXPIRATION DATE.
Surgical implants should not be reused. Any implant once used should be discarded. Even though it may appear undamaged, it may have small defects or internal stress patterns, which may lead to failure.

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 HTR® Implant 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 HTR® Implant 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	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".

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