HammerTube™ System

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION.

A FULL SYMBOLS GLOSSARY CAN BE FOUND AT: www.paragon28.com/resources

Please check the website, www.paragon28.com/ifus, for the most current instructions for use document.

This booklet is designed to assist in using the HammerTube™ System. It is not a reference for surgical techniques.

CAUTION
Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

GENERAL DESCRIPTION
The HammerTube™ System is comprised of a sterile, PEEK (Polyetheretherketone) fixation device and stainless steel K-wires. The PEEK implants are offered in diameters of Ø2.75mm and Ø3.50mm, with 0° and 10° angled options. The K-wires range in diameters from Ø1.1mm to Ø1.8mm. The system instruments include inserters, drills, planers, trephine removal tool, and a threaded extractor.

MATERIALS
The dowels are manufactured from PEEK per ASTM F2026 with a titanium plasma spray that conforms to ASTM F1580. The K-wires are manufactured from Stainless Steel per ASTM F138. The instrumentation is manufactured from medical grade stainless steels and plastics.

INDICATIONS FOR USE
The HammerTube™ System is indicated for fixation of reconstruction and fusion of toes during correction procedures for hammertoe deformity, claw toe deformity, shortening osteotomies of the phalanges and mallet toe deformity as well as revision hammertoe procedures.

The cannulated and solid HammerTube™ implants may be used without any other additional device. The cannulated implants may be used with K-wires for delivery of implants or for the temporary stabilization of nearby joints, such as the metatarsophalangeal joint.

The implantable K-wires are indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation, appropriate for the size of the joint. Additionally, the implantable K-wires are indicated as guide pins for insertion of instruments and implants in the HammerTube™ System.

CONTRAINDICATIONS
The HammerTube™ System is contraindicated for use in patients with an active or suspected infection; in patients who are physiologically or psychologically inadequate; in patients previously sensitized to titanium; in patients with insufficient quantity or quality of bone to permit stabilization of the bony segments; in patients with high level of activity; or where there is a possibility for conservative treatment.

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS
In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:
- Loosening, deformation or fracture of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as a result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28®, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS
- 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.
- Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments and K-wires are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the HammerTube™ System.**
- **Do not re-sterilize the HammerTube™ System sterile implants or sterile instrumentation.**

MR SAFETY INFORMATION

MRI Safety Information 

A patient with the Paragon 28® HammerTube™ System may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Indentification of device	Paragon 28® HammerTube™ System
Nominal value(s) of Static Magnetic Field [T]	1.5 T or 3 T
Maximum Spatial Field Gradient [T/m and gauss/cm]	12 T/m (1200 gauss, cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole Body SAW [W/kg]	2.0 W/kg (Normal Operating Mode)
Limits on Scan Duration	2.0 W/kg whole body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks)

If information about a specific parameter is not included, there are no conditions associated with that parameter.

MAINTAING DEVICE EFFECTIVENESS
- The surgeon should have specific training, experience, and thorough familiarity with the use of fixation devices.
- The surgeon must exercise reasonable judgment when deciding which implant type to use for specific indications.
- The HammerTube™ implants are not intended to endure excessive abnormal functional stresses.
- The HammerTube™ implants are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique HammerTube™ System 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.
- Carefully inspect the implants prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc. products in a sterile environment.

HANDLING AND STERILIZATION
STERILE IMPLANTS, INSTRUMENTS, AND KITS

Paragon 28® HammerTube™ System is provided in either an implant-only, an instrument-only, or a sterile kit configuration that includes an implant and instrumentation. They are provided sterile by exposure to a minimum dose of 25 kGy of gamma radiation. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of device includes potential for patient to develop infection. Do not use implants or instruments after expiration date. Packaging should be intact upon receipt.

Sterile packaging should be inspected to ensure that the package has not been damaged or previously opened. If the inner package integrity has been compromised, **DO NOT USE THE IMPLANT AND/OR INSTRUMENTS**. Contact the manufacturer for further instructions. The packaging should be opened using aseptic techniques. The implant and/or instrumentation should only be opened after the correct size has been determined. Once the seal of the product is broken, the product should not be re-sterilized.

All sterile packed product should be stored in a clean, dry environment.

NON-STERILE PRODUCT

Product that is presented in a tray is provided non-sterile. All non-sterile implants and instruments should be cleaned using established hospital methods before sterilization and introduction into the sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Paragon 28®, Inc. ***Instrument Reprocessing Instructions for Reusable Instruments*** (P20-CLN-0001). This is also available by calling (855) 786-2828.

3D PRINTED NYLON INSERTERS

The HammerTube 3D printed inserters are single use, supplied non-sterile and should be cleaned using the following validated cleaning method:

1. Prepare neutral pH enzymatic detergent solution following the manufacturer's recommendation.
2. Fully immerse the device into the prepared detergent and allow the device to soak for 5 minutes.
3. While immersed, use a soft bristle brush to brush this device, paying particular attention to crevices and other hard to reach areas.
4. Use a syringe to flush the holes or lumens and any difficult to reach areas.
5. Rinse the device under running reverse osmosis – deionized water (RO/DI) at ambient temperature.
6. While rinsing, use a syringe to flush the holes and difficult to reach areas.
7. Wipe dry with sterilized lint free cloth or wipes.

Following cleaning, the instruments MUST be sterilized prior to use.

NOTE: The sub-components shall not be assembled until AFTER they have been sterilized to prevent situations where condensation from the sterilization could get trapped.

Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap is recommended. The following validated steam autoclave cycle is recommended:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270° F (132° C)	4 Minutes	30 Minutes

INSTRUCTIONS FOR USE

Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant the HammerTube™ System. Refer to the HammerTube™ System Surgical Technique (P40-STG-0001) for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28®, Inc. by phone, (855) 786-2828.

IMPLANT REMOVAL

- Instrumentation can be provided for implant removal.
- Removal instructions are provided in the HammerTube™ System Surgical Technique (P40-STG-0001).

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Paragon 28®, Inc. immediately. Paragon 28®, Inc. should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

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

Paragon 28, Inc.
14445 Grasslands Dr.,
Englewood, CO 80112
USA
(855) 786-2828

Patient implant card

Print information

Print true to size (100% scale) with minimal margins

Step 1

Cut along solid line

Step 2

Fold paper vertically

Step 3

Fold paper horizontally