Exclusively foot & ankle Paragon 28®

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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.

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 Ø1.6mm. The system instruments include inserters, drills, planers, trephine removal tool, and a threaded extractor.

INTENDED/ EXPECTED CLINICAL BENEFITS

The intended clinical benefits of the HammerTube™ System are:

- Successful implantation of HammerTube™ System devices
- Deformity Correction
- Improvement in Pain
- Improvement in Function

The Summary of Safety and Clinical Performance (SSCP) can be found at:

https://ec.europa.eu/tools/eudamed by searching for Manufacturer: Paragon 28 (upon Eudamed activation). Until Eudamed is activated, to request a copy of the SSCP, please contact Paragon 28®, Inc. by phone, (+1) (855) 786-2828.

Residual Risks identified within the SSCP are included as warnings and precautions.

IMPLANT MATERIALS

The HammerTube™ System (PEEK) implants are made from PEEK polymer per ASTM F2026 with a titanium plasma spray that conforms to ASTM F1580.

The maximum possible composition of each element is as follows:

PEEK polymer per ASTM F2026	
Element	**Maximum Composition, % (Mass/Mass)**
Polyetheretherketone (PEEK)	100

Titanium Plasma Spray per ASTM F1580	
Element	**Maximum Composition, % (Mass/Mass)**
Nitrogen	0.05
Carbon	0.08
Hydrogen	0.05
Iron	0.50
Oxygen	0.40
Cobalt	0.10
Other (each)	0.10
Other (Total)	0.40
Titanium	98.42

The K-wires are manufactured from 316 LVM Stainless Steel per ASTM F138. The maximum possible composition of each element is as follows:

Stainless Steel per ASTM F138	
Element	**Maximum Composition, % (Mass/Mass)**
Carbon	0.030
Manganese	2.00
Phosphorous	0.025
Sulfur	0.010
Silicon	0.75
Chromium	19.00
Nickel	15.00
Molybdenum	3.00
Nitrogen	0.10
Copper	0.50
Cobalt	0.10
Iron	64.235

INSTRUMENT MATERIALS

The instrumentation is made from medical grades of stainless steel and plastics.

CMR, EDP, PHTHALATES

The HammerTube™ System Implants & Surgically Invasive Instruments do not contain substances ≥0.1% (w/w) which are classified as carcinogenic, mutagenic or toxic to reproduction (CMR), substances ≥0.1% (w/w) which have endocrine disrupting properties (EDP) and do not contain phthalates.

INTENDED USE/ INTENDED PURPOSE

The HammerTube™ System is intended for use in the fixation of hammertoe correction including fusion, reconstruction, and revision procedures. The HammerTube™ implants may be used without any other additional device. The implants may be used with K-wires for delivery of implants or for the temporary stabilization of nearby joints, such as the distal interphalangeal joint and metatarsophalangeal joint.

INDICATIONS FOR USE

The HammerTube™ System is intended for use in the fixation of hammertoe correction including fusion, reconstruction, and revision procedures.

Device	Indications for Use
HammerTube™ Implants	HammerTube™ Implants are Indicated for Primary and Revision Hammertoe Correction Procedures for: Hammertoe Deformity Malunion or Nonunion of Previous Digital Surgery
HammerTube™ System Implantable K-wires	The HammerTube™ System Implantable K-wires are indicated for use with the straight cannulated HammerTube™ implant for the temporary (usually 4-6 weeks) stabilization and fixation of small bones in: • Hammertoe Deformity • Malunion or Nonunion of Previous Digital Surgery And/or the HammerTube™ System Implantable K-wires are indicated for use as removable guide pins for insertion of instruments and implants in the HammerTube™ System.

CONTRAINDICATIONS

Use of the HammerTube™ System is contraindicated in cases of inflammation, cases of active or suspected sepsis / infection and osteomyelitis, or in patients with certain metabolic diseases.

- Active or suspected infection in the affected area
- Patients who are physiologically or psychologically inadequate
- Patients with a known or suspected sensitivity to Titanium in the case of the PEEK dowel Implant.
- Patients with a known or suspected sensitivity to Nickel in the case of the Stainless-Steel K-Wire Implant.
- Patients with insufficient quantity or quality of bone to permit stabilization of the bony segments.
- Patients with a high level of activity; or where there is a possibility for conservative treatment.
- Indications not included in the **INDICATIONS FOR USE**

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. Any single use device which has been used may have come in contact with tissue, bone, blood or other bodily fluids. This is considered contaminated and must be discarded for the safety of the patient or other users. The reuse of a single use device could result in infection from inadequate sterilization or premature failure due to mechanical degradation resulting in the need for revision surgery.
- 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 implants.**
- In any surgical procedure, the potential for complications and adverse reactions exists. Adverse events include but are not limited to those described in this document. The risks, potential complications, and adverse reactions 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 or protracted 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
    - Delay or failure of bone healing
    - Loss of correction

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.

MR SAFETY INFORMATION

MRI Safety Information

A patient with a Paragon 28 Kirschner (K) Wire, HammerTube™ System PEEK implant, or K-Wire/HammerTube™ System PEEK implant construct may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

Name/Identification of device	Paragon 28 Kirschner (K) Wire, HammerTube™ System PEEK implant, or K-Wire/HammerTube™ System PEEK implant construct
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
Operating Mode	Normal Operating Mode
Maximum Whole Body SAR [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)
MR Image Artifact	The presence of this implant may produce an image artifact of 48 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

MAINTANING 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 fixation until osteogenesis occurs (typically 3 months).
- 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.
- If an instrument is damaged, contact Paragon 28® immediately to arrange replacement and/or disposal.
- Paragon28 non-sterile devices are precision medical devices and must be used and handled with care. Inspect the devices for damage prior to use, and at all stages of handling thereafter. If damage is detected, do not use the device prior to consulting the manufacturer for guidance.
- Devices with cutting functions or sharp points become dull with continuous use. This condition does not indicate a defective device and may indicate normal wear. Any sign of dull or wearing devices may require replacement if they no longer perform as designed. Inspection prior to use should include verifying the cutting ability and sharpness of these points and edges.
- Single use devices must not be re-used. Re-use of single use devices can result in injury to the surgeon and /or the patient. Specific risks include cross contamination, difficulty placing the implant and / or implant failure.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc. products in a sterile environment.

HANDLING AND STERILIZATION

Sterile Product:

Paragon 28® HammerTube™ implants are provided sterile using gamma irradiation. DO NOT re-sterilize. SINGLE USE ONLY. Any device labeled as Single Use only must never be reused or reprocessed. Any device opened from its packaging is considered used and may have come in contact with tissue, bone, blood or other bodily fluids. This is considered contaminated and must be discarded for the safety of the patient and other users. Do not use implants after expiration date. Packages for implants should be intact upon receipt.

Implants in 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. Contact the manufacturer for further instructions. The implants should be opened using aseptic technique. The implant 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 implants 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 (Manual Method P99-CLN-0001) (Automated Method P99-CLN-1001). For product information or to obtain a copy of the surgical technique manual and/or the Summary of safety and clinical performance, please contact Paragon 28®, Inc by calling (+1) (855) 786-2828.

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 2 layers of sterilization wrap is recommended. The following validated steam autoclave cycle is recommended:

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

INTENDED USERS

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-1001) 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, (+1) (855) 786-2828.

IMPLANT REMOVAL (IF NECESSARY)

- Instrumentation can be provided for implant removal.
- Removal instructions are provided in the HammerTube™ System Surgical Technique (P40-STG-1001).

TARGETED POPULATION

The HammerTube™ System is intended for members of the adult general population who are under the care of a physician who determines the need for surgical hammertoe correction. The population does not include patients that are pregnant nor any others with conditions listed in the contraindications.

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., or its EC Representative 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.

DISPOSAL OF IMPLANT OR INSTRUMENT

The implant and associated instrumentation will be used in a surgical suite, and thus, any disposal of the implant(s), instrument(s), and/or packaging will occur in the surgical suite by the user.

- The sterile packaged implant will be opened in the surgical suite with the packaging disposed of by the user. The outside packaging is not passed onto the operative field and should not be contaminated by human tissue or blood. The outside packaging is disposed of in a standard waste receptacle. If the inner packaging is in contact with human tissue or blood, the inner packaging must be disposed of in a standard biowaste container. If the inner packaging does not come in contact with human tissue or blood, the inner packaging can be disposed of in a standard waste receptacle.
- In the case of an implant removal, or if an implant must be disposed of during surgery, the disposal will occur in the surgical suite by the user. Because the implant has been in contact with human tissue or blood and may have a sharp physical hazard, the implant must be disposed of in a biohazard waste container intended for sharps.
- In the case of instrument disposal, the disposal will occur in the surgical suite by the user. Because the instrument has been in contact with human tissue or blood and may have a sharp physical hazard, the instrument must be disposed of in a biohazard container intended for sharps

Please contact Paragon 28®, Inc. for product inquiries, cleaning instructions and surgical techniques. To report any adverse event, please contact Paragon 28®, Inc. or its EC Representative.

	EC REP	UK Responsible Person	CH REP
Paragon 28, Inc. 14445 Grasslands Dr., Englewood, CO 80112 USA **(+1) (855) 786 - 2828**	**Emergo Europe Westervoortsedijk 60 6827 AT Arnhem The Netherlands**	**MedEnvoy UK Ltd 85 Great Portland St. London, W1W 7LT, UK**	**Zimmer GmbH Zählerweg 4 6300 Zug Switzerland**

CE 2797	**Class Ir, IIa, IIb**
CE	**Class I Self Certify**

Basic UDI-DI information
0889795P40IIB01GSUCMCY (Sterile Packed Implants)
0889795P40IIB01NSUCMFD (Non-Sterile Packed Implants)