Monkey Rings™ External Fixation 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 Monkey Rings™ External Fixation 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 Monkey Rings™ External Fixation System is comprised of multiple components to facilitate the appropriate external construct for the intended use. Schanze screws and wires are implanted in bone and the other ends are clamped to external rings. Rods, struts, posts, plates, bolts, and wires are provided in various sizes to complete the construct.

MATERIALS

The implants of the Monkey Rings™ External Fixation System are made from stainless steel and titanium alloy. The instrumentation is manufactured from medical grades of stainless steel, plastic, rubber, aluminum, carbon fiber reinforced polyether ether ketone, titanium, and carbon steel.

INDICATIONS FOR USE

The Monkey Rings™ External Fixation System is indicated in pediatric patients and adults for the treatment and fixation of:

- Open and closed fractures
- Post-traumatic joint contracture which has resulted in loss of range of motion
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction
- Pseudoarthrosis, infected union, non-union, or malunion of long bones
- Limb lengthening by epiphyseal, diaphyseal, or metaphyseal distraction
- Correction of bony or soft tissue deformity (e.g. orthoplastic surgery)
- Correction of segmental bony or soft tissue defects
- Joint arthrodesis
- Management of comminuted intra-articular fractures
- Bone transport

The Monkey Rings™ External Fixation System is indicated in adults for:

- Osteotomy
- Revision procedure where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot foot reconstruction
- Offloading and/or immobilization of ulcers and/or wounds of the foot and ankle
- Lisfranc dislocations
- Ankle distraction (arthrodiastasis)
- Septic fusion

CONTRAINDICATIONS

Since external fixation devices are often used in emergency situations to treat patients with acute injuries, there are no absolute contraindications for use. The surgeon's education, training and professional judgment must be relied upon to choose the most appropriate device and treatment for each individual patient. Whenever possible, the device chosen should be of a type indicated for the fracture being treated and/or for the procedure being utilized. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic, and patients with a history of infection
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the devices
- Osteopathies with reduced bone substance that could affect the function of the devices
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment. The risk of breakage of a fixation device is greater in older patients with mental deficiency, alcoholics or drug addicts or patients who, for other reasons, may ignore the necessary restrictions and precautions to be observed while using the device.
- Known or suspected sensitivity to device materials
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or device failure can occur

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, migration, subluxation, fracture of the device, or premature loss of fixation with the bone which may result in nerve and soft tissue damage
- Delayed union, non-union, or malunion resulting in breakage of the construct. If healing is delayed, or does not occur, the construct may eventually break due to the increased loading.
- Acute post-operative wound infections and late infections with possible sepsis and osteomyelitis, including chronic drainage of the Schanze screw sites following removal of the device.
- Migration, subluxation of the implant with resulting reduction in range of movement
- Thrombosis or embolism
- Avascular necrosis
- Tissue necrosis, wound hematoma and delayed wound healing
- Excessive surgical bleeding
- Temporary and protracted functional neurological perturbation
- Tissue reactions as the result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized tissue reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding
- Shortening of the affected bone/fracture site.
- Bone loss or reduced bone density due to a reduction in the tension applied to the bone.
- Fractures resulting from unilateral joint loading
- Edema or possible compartmental syndrome.
- Premature bone callus consolidation during distraction.
- Possible tension affecting the soft tissues and/or the fixation during manipulation of the callus (e.g. corrections of deformities and/or elongation).
- Fracture of regenerated bone, or at the Schanze screw holes, following removal of the device.
- Bone damage due to erroneous Schanze screw selection.
- Bone deformities or talipes equinus.
- The persistence or recurrence of the initial condition subject to treatment.
- Abnormal growth cartilage development in skeletally immature patients.
- Pressure on the skin caused by external components when the free space is insufficient.
- Secondary bony sequestration due to rapid perforation of the cortex with accumulation of heat and bone necrosis.
- Nerve or vascular damage following the insertion of Schanze screws or wires.

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® in the event that 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® with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28® 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 non-compliant patient behavior.

WARNINGS AND PRECAUTIONS

- The patient must be informed that a second minor surgery for the removal of the fixation system is required.

- 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.
- The implants and guide wires are intended for single use only.
- Guide wires and Schanze screws are to be treated as sharps.
- **Do not reuse single use devices.** Reuse of single-use external fixators may lead to reduced biomechanical properties and/or fatigue breakage of the devices.
- **Do not use other manufacturer's instruments or implants in conjunction with the Monkey Rings™ External Fixation System.**

MR SAFETY INFORMATION

The Monkey Rings™ External Fixation System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of Monkey Rings™ External Fixation System in the MR environment is unknown. Performing an MR exam on a person who has this medical device may result in injury or device malfunction.

MAINTANING DEVICE EFFECTIVENESS

- The product is intended for use by Healthcare Professionals only. The surgeon should have specific training, experience, and thorough familiarity with the device.
- The surgeon must exercise reasonable judgment when deciding to use the device.
- Surgeons must instruct the patients to report any unusual changes of the operated site to their physician. Surgeon should immediately evaluate the patient if a change at the fracture site has been detected. The surgeon should evaluate the possibility of subsequent clinical failure, and discuss with the patient the need for reduced activity levels, and / or possible revision surgery in order to aid fracture healing.
- The surgeon should check the status of the Schanze screws and the fixation at regular intervals. The fracture or bone gap must be checked periodically during treatment, making any necessary adjustments to the fixation. An excessive or persistent gap can delay consolidation.
- The surgeon should discuss all physical and psychological limitations inherent in the use of external fracture fixation appliances with the patient. Particular attention should be given to premature weight bearing, activity levels and the necessity for periodic medical follow-up.
- If the patient's activity comprises significant impact loads (lifting or heavy muscular activity) the resulting forces could lead to failure of the fixation, the system or both. The system will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
- Ensure the implant sites are kept meticulously clean. The patient must be instructed regarding the use and maintenance of the fixation and care of the Schanze screw sites.
- The Monkey Rings™ External Fixation System is not intended to endure excessive abnormal functional stresses.
- The Monkey Rings™ External Fixation System is intended for temporary fixation only until bone healing occurs.
- Failure to use dedicated, unique Monkey Rings™ External Fixation 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 external fixators prior to use and 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 Product:

Paragon 28® Monkey Rings™ External Fixation System product provided sterile are sterilized using gamma irradiation. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of the device includes potential for patient to develop infection. Do not use devices after expiration date. Packages for product must be intact upon receipt.

Product 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 DEVICE. Contact the manufacturer for further instructions. The product should be opened using aseptic technique. Once the seal of the product is broken, the product should not be re-sterilized.

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

Non-Sterile Product:

Product that is presented in a caddy is provided non-sterile. Non-sterile product must first 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 Monkey Rings™ External Fixation System Instruments*** (P45-CLN-0001). This is also available by calling (855) 786-2828.

Unless specifically labeled sterile, the devices 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 is recommended:

DEVICE REMOVAL

- Instrumentation can be provided for device removal.
- Removal instructions are provided in the Monkey Rings™ External Fixation System Surgical Technique (P45-STG-0001).

Recommended Steam Sterilization Parameters				
Device Set	**Cycle**	**Temperature**	**Exposure Time**	**Dry Time**
EXCIR1	Pre-vacuum	270°F (132°C)	4 Min	50 Min
	Pre-vacuum[1]	273°F (134°C)	3 Min	
EXCIR2	Pre-vacuum	270°F (132°C)	4 Min	30 Min
	Pre-vacuum[1]	273°F (134°C)	3 Min	
EXCIR3	Pre-vacuum	270°F (132°C)	4 Min	30 Min
	Pre-vacuum[1]	273°F (134°C)	3 Min	
EXCIR4	Pre-vacuum	270°F (132°C)	4 Min	30 Min
	Pre-vacuum[1]	273°F (134°C)	3 Min	
Pre-Built Frame inside EXCIR1	Pre-vacuum	270°F (132°C)	4 Min	40 Min
	Pre-vacuum[1]	273°F (134°C)	3 Min	

[1] 134°C setting is for outside the USA only

Pin cutters may be supplied separately and should be wrapped using (2) layers of CSR per AAMI ST79 and secured with SPS medical sterilization tape.

INSTRUCTIONS FOR USE

Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant the Monkey Rings™ External Fixation System. Refer to the Monkey Rings™ External Fixation System Surgical Technique P45-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.

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, cleaning instructions and surgical techniques, or to report any adverse event.

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