



Monkey Bars Pin to Bar 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 Bars Pin to Bar 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 Bars Pin to Bar External Fixation System is used for the external stabilization of bone fractures. It consists of clamps, bars, posts, pins, and other devices. The pins are implanted into bone and are connected using the clamps, rods and posts to form a rigid construct which holds the bone fragments rigidly in place.

MATERIALS

The implants of the Monkey Bars Pin to Bar External Fixation System are made from stainless steel. The instrumentation is manufactured from medical grades of stainless steel, aluminum, carbon fiber composite and titanium.

INDICATIONS FOR USE

The Monkey Bars Pin to Bar External Fixation System intended to be used in adult and pediatric patients (specifically, children and adolescents aged 2 through 21 years) for provisional fixation of open and/or unstable fractures in the lower and upper extremities and pelvis. It may also be used for temporary fixation of peri-articular or intra-articular fractures. Additionally, the device can be used on fractures where soft tissue injury or an infected fracture site may preclude the use of other fracture fixation treatments.

CONTRAINDICATIONS

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:

- Mental conditions that preclude cooperation with the rehabilitation regimen.
- Patients with bone conditions or fracture patterns that prevent secure implantation of multiple pins in the coronal plane.
- Patients with metal allergy that precludes use of stainless steel pins or instruments.
- 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
- 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 exists. The risks and complications with these devices include:

- Loosening, bending, cracking or fracture of the implant or components.
- Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation.
- Infections, both deep and superficial.
- Irritational injury of soft tissues, including impingement syndrome.
- Tissue reactions which include macrophage and foreign body reactions adjacent to implants.
- Metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.
- 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
- 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 pin holes, following removal of the device.
- Bone damage due to erroneous pin 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 pins.

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 bone should be drilled slowly so that heat buildup does not cause tissue or bone necrosis.
- Pin placement should avoid locations that will lead to damage to muscles, tendons, vessels or nerves.
- Use care when handling sharp pin, trocar and drill tips.
- 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.
- 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 Bars Pin to Bar External Fixation System.
- The device should only be used in pediatric patients where the growth plates have fused or in which active growth plates will not be crossed by the system implants or instrumentation. When used for pediatric patients with

active growth plates, implants must be placed at least 2cm from the growth plate.

MR SAFETY INFORMATION

<div><div>MRI Safety Information</div><p>A patient with the Monkey Bars Pin to Bar External Fixation System, with the device to remain outside the RF body coil, specifically, the edge of the device must be >40 cm from the landmarked iso-center, may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.</p></div>	
Device Name	Monkey Bars Pin to Bar External Fixation System
Additional instructions for information essential for safe use in the MR environment	Device must remain outside of RF body coil. Specifically, the edge of the device must be >40 cm from the landmarked iso-center.
Nominal value(s) of Static Magnetic Field [T]	1.5T or 3.0T
Maximum Spatial Field Gradient [T/m and gauss/cm]	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Whole body transmit coil, Head RF transmit-receive coil
Maximum Whole-Body SAR [W/kg]	2 W/kg (Normal Operating Mode)
Maximum Head SAR [W/kg]	3.2 W/kg (Normal Operating Mode)
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.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

MAINTAINING DEVICE EFFECTIVENESS

After completion of procedure all pin sites should be inspected to ensure there is no skin tenting or soft tissue impingement. Sterile dressings can be placed around pins to prevent bleeding or hematoma formation. We recommend daily cleaning with soap and water, chlorhexidine or alcohol.

Care Prior to Bony Union: Postoperative follow-ups and radiographs are recommended. Early weight bearing substantially increases implant loading and increases the risk of loosening, bending or breaking the device. Early weight bearing should only be considered where there are stable fractures with good bone-to-bone contact and should not be considered for patients who are obese and/or noncompliant, as well as patients who could be predisposed to delayed or non-union. Patients and nursing care providers should be advised of these risks.

Care Subsequent to Bony Union: Even after bony union, the patient should be cautioned that a fracture is more likely with the device in place and soon after its removal, rather than later, when voids in the bone left by implant removal have been filled in completely. Patients should be cautioned against unassisted activity that requires walking or lifting. Postoperative care and physical therapy should be structured to prevent loading of the operative extremity until stability is evident. Additional postoperative precautions should be taken when the fracture line occurs within 5 cm of the voids left after removal of the pins.

Implant Removal. The operating surgeon will make final recommendations regarding removal of implants, considering all facts and circumstances. After bone healing is observed, the device serves no purpose and must be removed.

Patients should be directed to seek medical opinion before entering potentially adverse environments that could affect the performance of the implant, such as electromagnetic or magnetic fields, including a magnetic resonance environment.

CLEANING AND DECONTAMINATION

Product that is presented in a caddy is provided non-sterile. Nonsterile 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 Instruments P99-CLN-0001. This is also available by calling (855) 786-2828.

HANDLING AND STERILIZATION

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:

Cycle	Temperature	Exposure Time	Dry Time
Pre-vacuum	270°F (132°C)	4 Min	30 minutes

Store in a cool dry place and keep away from direct sunlight.

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 Bars Pin to Bar External Fixation System External Fixation System. Refer to the Monkey Bars Pin to Bar External Fixation System Surgical Technique P85-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.



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