Monkey Bars™ Pin to Bar External Fixation System

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.

IMPORTANT MEDICAL INFORMATION

INDICATIONS

The Monkey Bars™ Pin to Bar External Fixation System is intended to be used in adult and pediatric patients 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

1. Mental conditions that preclude cooperation with the rehabilitation regimen.
2. Patients with bone conditions or fracture patterns that prevent secure implantation of multiple pins in the coronal plane.
3. Patients with metal allergy that precludes use of stainless steel pins or instruments.

WARNINGS

1. The bone should be drilled slowly so that heat buildup does not cause tissue or bone necrosis.
2. Pin placement should avoid locations that will lead to damage to muscles, tendons, vessels or nerves.
3. Use care when handling sharp pin, trocar and drill tips.

PREOPERATIVE PLANNING

1. Surgical Technique. Correct surgical technique is essential to a successful outcome. Proper reduction of fractures and proper placement of implants are necessary to effectively treat patients using metallic surgical implants. Please review the surgical technique for effective surgical procedures.
2. Implant and External Component Selection. Proper type and size of implants and components must be selected to insure effective treatment of patients. The following factors should be considered:
   - A patient's size, strength, skeletal characteristics, skeletal health, and general health. Overweight or musculoskeletally deficient or unhealthy patients may create greater loads on implants that may lead to breakage or other failure of the device.
   - A patient's activity level during the time the implant is in the patient's body, including such factors as whether the patient's occupation or typical activities include running, heavy lifting, impact loading, or the like.
   - Whether a patient has a degenerative or progressive disease that delays or prevents healing and leads to exceeding the effective life of the device.
   - If a patient is suspected of having material or foreign body sensitivities, appropriate testing should be accomplished prior to implantation.
   - Mental conditions or substance abuse problems that may prevent a patient from understanding or following directions or observing precautions.
3. Device Alterations. The ends of the pins protruding beyond the clamps after the system is assembled may be cut to reduce excess length. Hold the end of the pin when cutting. Cover the protruding ends of the pins with pin caps. Other than cutting the ends of the pins, the components are not designed to be physically altered, bent, notched, gouged, reamed, scratched or cut.
4. Component Compatibility. Components such as clamps, rods, pins and posts are available in many styles and sizes and are manufactured from various types of metals. The component material is provided on the outside carton label. Do not mix components from different manufacturers.
5. Implant Removal. The patient should be advised that a second procedure for the removal of implants will be necessary.

POSTOPERATIVE CARE

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 pre-disposed 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.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the Monkey Bars™ Pin to Bar External Fixation System is MR Conditional for use external to the scanner bore. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial field gradient of 1,180 G/cm (11.8 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg.
- Implant should be located outside the scanner bore.

RF heating - Under the scan conditions defined above, the Monkey Bars™ Pin to Bar External Fixation System is expected to produce a maximum temperature rise of less than 1 ºC after 15 minutes of continuous scanning.
MR Artifact - In non-clinical testing, the image artifact caused by the device is not detectable when the Monkey Bars™ Pin to Bar External Fixation System is located outside the scanner bore.

NO REUSE

Surgical implants and components are NEVER TO BE REUSED. Stresses and fractures, even though not noticeable by visual inspection, may have been created during implantation or use. Single use devices should not be reused due to risks of breakage, failure or patient infection.

POSSIBLE ADVERSE EFFECTS

1. Loosening, bending, cracking or fracture of the implant or components.
2. Limb shortening or loss of anatomic position with nonunion or malunion with rotation or angulation.
3. Infections, both deep and superficial.
4. Irritational injury of soft tissues, including impingement syndrome.
5. Tissue reactions which include macrophage and foreign body reactions adjacent to implants.
6. Metal sensitivity reactions and/or allergic reactions to foreign materials have been reported in patients.

PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. If the

factory packaging has been opened return the component to Paragon 28, Inc.

STERILIZATION

Implants and components are supplied non-sterile and must be cleaned and sterilized prior to surgery. For non-sterile trauma implants (i.e. pins) remove all original packaging and labeling inserts prior to sterilization. It is important that adequate cleaning be carried out prior to sterilization. New implants and instruments must be thoroughly cleaned before initial sterilization. Trained personnel must perform cleaning (manual and/or machine cleaning, ultrasound treatment, etc.) along with maintenance and mechanical inspection prior to initial sterilization. Exact compliance with the equipment manufacturers' user instructions and recommendations for chemical detergents is required. Do not stack trays during sterilization.

LIMITS ON REPROCESSING:

Repeated processing cycles that include ultrasonic, mechanical washing and sterilization have minimal effects on the Monkey Bars™ Pin to Bar External Fixation System implants and instruments. Implants and instruments should be inspected for damage such as corrosion, scratches, notches, debris, visible wear, discoloration or residue. Damaged implants and instruments should be discarded.

CLEANING OF INSTRUMENTS:

1. Within a maximum of two (2) hours after use, remove gross soil using absorbent paper wipes. Rinse with warm (>45°C) tap water for two (2) minutes. Flush cannulated devices thoroughly to prevent the drying of soil and/or debris to the inside.
2. If cleaning must be delayed, place instruments in a covered container with appropriate detergent (Enzol® Enzymatic Detergent or equivalent) to delay drying.
3. Disassemble device if possible prior to cleaning. Detailed instructions for assembling and disassembling the instruments are contained in the surgical technique guide.
4. Tap water used for cleaning and rinsing will meet the characteristics for potable water in AAMI TIR34. Deionized and high purity water will meet the characteristics listed in AAMI TIR34.

Manual Cleaning:

1. Rinse soiled device under running cold (<45°C) tap water for a minimum of two minutes. Use a soft bristled brush to assist in the removal of gross soil and debris
2. Soak device in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality and concentration.
3. Rinse device with cold (<45°C) tap water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels and other hard to reach areas.
4. Manually clean device for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft bristled brush to remove soil and debris. Actuate joints, handles and other moveable device features to expose all areas to the detergent solution.
5. Rinse device thoroughly with cold (<45°C) deionized or high purity water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles and other moveable devices.

Automated Cleaning:

1. Pre-Treatment is required for any instrument(s) heavily soiled and/or containing dried organic material:
   Add one (1) ounce of Enzol® (or equivalent) to one (1) gallon of cold (<45°C) tap water. Using a soft bristle brush, clean the instrument thoroughly, paying particular attention to rough surfaces and features where soil may be impacted or shielded from the cleaning process. Rinse in warm (>45°C) running tap water until all traces of cleaning solution are removed. Visually inspect for any remaining soil and repeat the above steps if necessary. Allow to dry, and then transfer to the cleaning step.
2. Ultrasonic Clean (if required)
   Add one (1) ounce of Enzol (or equivalent) and one (1) gallon of warm (>45°C) tap water to an ultrasonic cleaner. Completely submerge instruments and sonicate for ten (10) minutes.
3. Ultrasonic Rinse
   To remove the detergent, thoroughly rinse each instrument with cold (<45°C) deionized water including all holes and cannulations. Inspect each instrument for evidence or organic matter. Repeat the sonication and rinse if needed.
4. Automated Washer
   Place instrument(s) in an automated washer (e.g. Steris Reliance® 444 Washer/Disinfector or equivalent). Load instruments such that contact is avoided, and articulating instruments are in the open position.

Automated Cleaning Parameters

Step	Time mm:ss	Minimum Temp °C	Cleaning Agent
Enzymatic Wash	04:00	49 °C Tap Water	Steris Prolystica 2X Concentrate (or equivalent) (1/8 oz./gal)
Wash	02:00	65.5°C Tap Water	Steris Prolystica 2X Concentrate Alkaline Cleaner (or equivalent) (1/8 oz./gal)
Rinse	02:00	70°C	Deionized or High Purity water
Dry	15:00	80°C	Not Applicable

Inspection

Visually inspect each instrument for evidence of organic matter. Repeat the cleaning process if necessary. If instruments are wet, use a lint-free wipe to dry.

STERILIZATION METHODS

Pre-vacuum autoclave Temperature:
270° F (132° C) for 4 minutes
Dry Time: 30 minutes

- Please consider your sterilization equipment manufacturer's written instructions for the specific sterilizer and load configuration used.
- Follow current AORN "Recommended Practices for Sterilization in Perioperative Practice Settings" and ANSI/AAMI ST79: 2006 "Comprehensive guide to steam sterilization and sterility assurance in health care facilities".
- Flash sterilization is not recommended, but if used, should only be performed according to requirements of ANSI/AAMI ST79: 2006 – Comprehensive guide to steam sterilization and sterility assurance in health care facilities.
- The devices should be sterilized using an FDA cleared wrap indicated for these sterilization cycles.

STORAGE INSTRUCTIONS

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

CAUTION: FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN

INFORMATION

For more information about products, please visit www.paragon28.com or contact Customer Service at (855) 786-2828.

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