



The Brachiator Mini 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 Brachiator Mini External Fixation System. It is not a reference for surgical techniques.

GENERAL DESCRIPTION

The External Fixation Mini Rail System consists of Schanz pins, rails, and pin clamps. The mini rail frame serves as the structural base for fixation distraction. The pin clamps allow rotational and translational positioning of bone segments. The system is meant to offer a solution for compression and gradual distraction of the metatarsals and 1st MTP joint. The system also includes instrumentation for implantation such as wires, drivers, sawblades, wrenches, templates and cut guides.

MATERIALS

The implants of the External Fixation Mini Rail System are made from stainless steel. The instrumentation is manufactured from medical grades of stainless steel, aluminum, silicone and nylon.

INTENDED USE/INDICATIONS FOR USE

The Brachiator Mini External Fixation System is intended for external fixation and is indicated for stabilization of fractures and osteotomy, foot arthrodesis, adult and pediatric leg lengthening, and correction of bone deformity in the lower extremities. When used in pediatrics, The Brachiator Mini External Fixation System is intended to be used in pediatric patients that are children aged 2 years to less than 12 years and adolescents aged 12 through 21 years (up to but not including the 22nd birthday).

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:

- 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
- Mental/physical conditions that preclude cooperation with the prescribed post-operative external fixator adjustment plan

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 Schanz pin 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 or over-lengthening 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 Schanz pin holes, following removal of the device.
- Bone damage due to erroneous Schanz 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 Schanz pins 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.

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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 Schanz pins are to be treated as sharps.
- 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.
- **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 Brachiator Mini External Fixation System.**

MR SAFETY INFORMATION

The Brachiator Mini 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 The Brachiator Mini 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 surgical 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 bone healing.
- The surgeon should check the status of the Schanz pins 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 Schanz pin sites.
 - The Brachiator Mini External Fixation System is not intended to endure excessive abnormal functional stresses.
 - The Brachiator Mini External Fixation System is intended for temporary fixation only until bone healing occurs.
 - Failure to use dedicated, unique The Brachiator Mini 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® The Brachiator Mini 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 Instruments** (P99-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:

Recommended Steam Sterilization Parameters			
Cycle	Temperature	Exposure Time	Dry Time
Pre-vacuum	270°F	4 Min	30 Min

DEVICE REMOVAL

- Instrumentation can be provided for device removal.
- Removal instructions are provided in The Brachiator Mini External Fixation System Surgical Technique (P46-STG- 0001).

INSTRUCTIONS FOR USE

Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant The Brachiator Mini External Fixation System. Refer to The Brachiator Mini External Fixation System Surgical Technique P46-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 Paragon 28® for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.

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



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