SPIDER MONKEY™ Bone Transport 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 Spider Monkey Bone Transport System. It is not a reference for surgical techniques.

GENERAL DESCRIPTION

The Paragon 28® Spider Monkey Bone Transport System consists of drills, pins, combination clamps, and distraction/compression external fixation device. The pins are implanted into bone and connected to the device via pin clamps and combination clamps to create a rigid construct that allows for discrete compression and distraction of a bone segment. The system is compatible with the Paragon 28® Monkey Rings and Monkey Bars systems.

MATERIALS

Spider Monkey Bone Transport System implants are made from stainless steel, The instrumentation for the Spider Monkey Bone Transport system is manufactured from stainless steel, aluminum alloy and High-performance Polymers.

INTENDED USE/INDICATIONS FOR USE

The Spider Monkey Bone Transport System is intended for treatment of non-union or pseudoarthrosis of long bones and correction of bony or soft tissue defects or deformities. The Spider Monkey Bone Transport System is indicated for adult and pediatric (greater than 2 through 21 years of age) patients.

CONTRAINDICATIONS

DO NOT USE the Spider Monkey Bone Transport System if a surgical candidate exhibits or is predisposed to any of the following contraindications:

- Mental or physiological conditions who are unwilling or incapable of following postoperative care instructions as it could result in a treatment failure in the intended population.

INTENDED PATIENTS

Proper patient selection and the patient's ability to comply with physician instructions and follow the prescribed treatment regimen will greatly affect the results. It is important to screen patients and select optimal therapy given physical and/or mental activity requirements and/or limitations. The Spider Monkey Bone Transport System is intended to be used in adult and pediatric (greater than 2 through 21 years of age) patients.

INTENDED USERS

The product is intended for use by Healthcare Professionals (HCP) only and such HCP must have full awareness of the appropriate orthopedic procedures and must be familiar with the devices, instruments and surgical procedures (including application and removal). During treatment, the Spider Monkey Bone Transport System is intended to be used by patient/caregiver as the system requires to perform gradual rotation of the Knob. Patients/Caregivers should refer to the Patient Quick Reference Guide (P38-QRG-0001) to understand use of the device, but should follow the treatment plan provided by their HCP

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:

- Non-union or delayed union, malunion
- Superficial infection
- Deep infection
- Loss of fixation
- Bending, breakage or migration of the device
- Additional surgery for soft tissue defects
- Reoperation to replace a component or entire frame configuration
- Bone fracture during or after treatment
- Bone loss or reduced bone density
- Damage to surrounding tissues due to surgical trauma
- Possible tension affecting the soft tissues and/or the frame during callus manipulation
- Wound healing complications
- Tissue necrosis
- Joint contracture, instability or loss of range of motion
- Arthritic changes
- Pain, discomfort or abnormal sensations due to the presence of the device
- Complex Regional Pain Syndrome
- Residual or new deformities
- Persistence or recurrence of the initial condition requiring treatment
- Premature bone callus consolidation during distraction
- Stiffness at surgery site
- Compartment syndrome
- Events caused by intrinsic risks associated with anesthesia and surgery

All possible complications listed here are not typical of Paragon 28® products but are in principle observed with any implant and/or surgical instrument. 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 product(s) in a clean, disinfected and sterile condition. Paragon 28® cannot accept used implants that that do not meet these criteria. 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

1. The template must be positioned within the medullary canal during fluoroscopy check.
2. During initial corticotomy do not cut all the sides of the bone segment.
3. Check that the template is positioned at least 40mm from the joint to allow the positioning of bicortical half pins in the static bar.
4. Utilizing fluoroscopy, ensure that the template is positioned within the medullary canal in order to ensure a unicortical transport segment.
5. Utilize the drill holes in the guide to pre-drill the long axis of the transport segment and ease sawing of the transport segment.
6. Visually check the correct insertion of the half pins in the first cortex using fluoroscopy.
7. In order to avoid instability of half pins inserted in the bone segment, perform provisional tightening of the clamping bolt before marking.
8. When loosening the clamping bolt for the transport segment half pin, take care not to push down the external fixator which could result in half pin instability.
9. When inserting the bi-cortical half pins, make sure that the half pins are placed through the external fixator or combination clamps.
10. Use fluoroscopy to check the correct insertion of the half pins in the second cortex.
11. Tighten the nuts of the external fixator before completing the corticotomy.
12. Before concluding the procedure, check that the transverse bone transport occurs correctly and that the nuts of the external fixator are securely tightened.
13. The surgeon must evaluate the integrity of the construct at follow-up visits.
14. The bone segment must be checked periodically during treatment, making any necessary adjustments to the fixation.
15. The surgeon shall provide instructions to the patient/caregiver with respect to the correct adjustments to be performed during the treatment.

All Paragon 28 devices should be used together with their corresponding Paragon 28 implants, components, accessories and instrumentation following the Surgical Technique recommended by the manufacturer. Paragon 28 does not guarantee the safety and effectiveness of the Spider Monkey Bone Transport System when used in conjunction with devices of other manufacturers or with other Paragon 28 devices if not specifically indicated in the Surgical Technique Guide (P38-STG-0001).

MR SAFETY INFORMATION

The Spider Monkey Bone Transport 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 Spider Monkey Bone Transport 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.

SPECIFIC INFORMATION ON THE DEVICE

To distract the bone segment, pull the knob and rotate counterclockwise (the direction of rotation is indicated by the arrow marked on the device). Note that the knob returns to a locked state after every quarter turn. During each turn (counterclockwise) the number of dots (from 1 to 4) aligned with the Paragon 28 logo will increase. Contrarily, to compress the bone segment, pull and rotate the knob clockwise. The device moves the bone segment of 0.25mm from the previous position every quarter turn.

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.
- Paragon 28® Inc. recommends the use of Paragon 28® Inc. products in a sterile environment.

HANDLING AND STERILIZATION

Sterile Product:

- Paragon 28® Spider Monkey Bone Transport System components that are labeled as sterile have undergone gamma irradiation. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of the device includes potential infection. Do not use devices after the labeled expiration date. 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.

Non-Sterile Product:

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

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.

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 Spider Monkey Bone Transport System Instruments(P99-CLN-0001). This is also available by calling (855) 786-2828.

DEVICE REMOVAL

- Once the treatment is complete, the implants must be removed. HCP should consider premature removal in case of adverse events.
- Instrumentation can be provided for device removal.
- Removal instructions are provided in the Spider Monkey Bone Transport System Surgical Technique Guide (P38-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 Spider Monkey Bone Transport System]. Refer to the Spider Monkey Bone Transport System Surgical Technique P38-STG-0001 for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28® by phone at (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® immediately. Paragon 28® 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.

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