

SIMPLE. EFFICIENT. VERSATILE.

To: Value Analysis Committee

From: Paragon 28° Product Development Team

Subject: Monkey Bars[™] Pin to Bar External Fixation System Launched

Date: January 10, 2022

CC: Technical Specialists, Engineering, Customer Service, Quality

Paragon 28 is pleased to announce the launch of the Monkey Bars™
Pin to Bar External Fixation System 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.

The Monkey Bars™ Pin to Bar External Fixation System offers a patent pending single clamp system that allows for bar-to-bar or bar-to-pin construction and has a multi-hole clamp option with straight and bent posts. It includes 3, 4, and 5mm self-tapping and blunt half-pins and contains carbon fiber bars. The product is manufactured from non-ferrous materials in the United States



Design Features

- ▶ **Pins:** Self drilling/self-tapping, or blunt tipped 3, 4, and 5mm stainless steel pins produced in a variety of thread and pin lengths. Both partially threaded half pins and a centrally threaded full pin are available.
- ► Clamps: Combination clamp system that allows for pin-to-bar and bar-to-bar fixation with 360 degrees of freedom.
- ▶ Multiple Pin Clamps: 5-hole and/or 8-hole clamps to ease construct creation and stability
- ▶ Posts: 0-degree and 30-degree posts for multiple pin clamps to provide construct versatility
- ▶ **Bars:** Carbon fiber 11mm bars





Applications

The Paragon 28® Monkey Bars™ External Fixation System allows for a wide variety of constructs including distal tibia and mid-shaft tibia fractures. The simplicity and ease of use of the external fixation system allows for quick and efficient application in the OR.

- Ankle Delta Frame
- ► Ankle Bridging Frame
- Distal Tibia Shaft Frame
- Midshaft Tibia Frame
- ▶ Femur Frame
- Knee Bridging Frame

SYSTEM COMPONENTS AND FEATURES



Combination Clamp:

Combination Clamps allow for Pin-to-Bar and Bar-to-Bar fixation with 360 degrees of freedom



Posts

O-degree Straight and 30-degree Angled posts for multiple Pin Clamps to provide construct versatility





8-Hole Pin Clamp 5-Hole Pin Clamp

Multiple Pin Clamps:

5-hole and/or 8-hole Clamps to streamline construct creation and enhance stability

Bars:

Carbon fiber 11mm diameter bar-length range 150mm to 500mm

Bar Sizes				
150mm P ³ (1mm x 150mm	200mm P3 11mm X 200mm	250mm P° 1111111 AZ5011111	300mm P° 111111 X300mm	
350mm P3 11mm X 380mm	400mm	450mm P ⁻³ Hnim X-450mm	500mm P3 11mm x 500mm	

ADDITIONAL SYSTEM INSTRUMENTATION















MONKEY BARS™ PIN TO BAR EXTERNAL FIXATION SYSTEM PART LIST

PART#	DESCRIPTION	QTY	
	Half Pins		
P47-210-320S	Half Pin, 3 x 20mn, Self-Tapping	4	
P47-210-320B	Half Pin, 3 x 20mm, Blunt-Tipped	4	
P47-210-420S	Half Pin, 4 x 20mm, Self-Tapping	5	
P47-210-420B	Half Pin, 4 x 20mm, Blunt-Tipped	5	
P47-210-430S	Half Pin, 4 x 30mm, Self-Tapping	5	
P47-210-430B	Half Pin, 4 x 30mm, Blunt-Tipped	5	
P47-210-535S	Half Pin, 5 x 35mm, Self-Tapping	6	
P47-210-535B	Half Pin, 5 x 35mm, Blunt-Tipped	6	
P47-210-545S	Half Pin, 5 x 45mm, Self-Tapping	6	
P47-210-545B	Half Pin, 5 x 45mm, Blunt-Tipped	6	
P47-210-555S	Half Pin, 5 x 55mm, Self-Tapping	6	
P47-210-555B	Half Pin, 5 x 55mm, Blunt-Tipped	6	
P47-210-565S	Half Pin, 5 x 65mm, Self-Tapping	6	
P47-210-565B	Half Pin, 5 x 65mm, Blunt-Tipped	6	
P47-220-5325	Transfixation Pin, 5 x 325mm, Centrally Threaded	2	
P47-230-0525	Pin Cap, 5mm	20	
	Clamps		
P47-310-1105	11mm Bar and 5mm Pin Combination Clamp	20	
P47-320-0005	5-Pin Multi Pin Clamp	2	
P47-320-0008	8-Pin Multi Pin Clamp	2	
	Bars		
P47-410-0150	Carbon Bar, 11mm x 150mm	3	
P47-410-0200	Carbon Bar, 11mm x 200mm	4	
P47-410-0250	Carbon Bar, 11mm x 250mm	4	
P47-410-0300	Carbon Bar, 11mm x 300mm	4	
P47-410-0350	Carbon Bar, 11mm x 350mm	4	
P47-410-0400	Carbon Bar, 11mm x 400mm	4	
P47-410-0450	Carbon Bar, 11mm x 450mm	4	
P47-410-0500	Carbon Bar, 11mm x 500mm	4	



MONKEY BARS™ PIN TO BAR EXTERNAL FIXATION SYSTEM PART LIST

PART #	DESCRIPTION	QTY
	Posts	
P47-510-P000	Straight Post	4
P47-510-P030	30 Degree Post	4
	Instruments	
P47-100-2414	Step Drill, 2.4 x 140mm	2
P47-100-3216	Step Drill, 3.2 x 165mm	2
P47-100-4020	Step Drill, 4.0 x 200mm	2
P47-910-0001	Fixation Pin Drill Sleeve w/ Handle	1
P47-920-0001	Fixation Pin Drill Sleeve	2
P47-930-0001	5mm Trocar	2
P47-940-0001	T-Handle, AO and 10mm Socket	1
P47-950-0001	10mm Combo Wrench	2
	Case	
P47-900-0001-1	Monkey Bars™ Sterilization Case Lid	1
P47-900-0001-2	Monkey Bars™ Sterilization Case Tray 1	1
P47-900-0001-3	Monkey Bars™ Sterilization Case Tray 2	1
P47-900-0001-4	Monkey Bars™ Sterilization Case Base	1

Thank you for your consideration of approval of the Monkey $\mathsf{Bars}^{\scriptscriptstyle{\mathsf{TM}}}$ Pin to Bar $\mathsf{External}$ $\mathsf{Fixation}$ System at your facility.

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Please reference the enclosed documents for additional product information:

- ▶ 510k
- Part List
- Surgical Technique



For additional information on Paragon 28° and its products please visit http://www.paragon28.com

P47-HRM-0001 RevA

For the IFU on this product, please visit: www.paragon28.com/ifus

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