



Baby Gorilla®/Gorilla® Plating 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 Baby Gorilla®/Gorilla® Plating 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 Baby Gorilla®/Gorilla® Plating System is comprised of plates, screws and washers used for bone fixation and stabilization. The bone plates are available in varying configurations (including, but not limited to, straight, curved, dog bone, rectangular, rhombus, 'T' plates, slanted 'T' plates, 'L' plates and ribbon plates) and varying lengths, which are attached to the bone using screw fixation. These plates are attached to bone using 2.0-4.2 mm diameter titanium self-tapping screws; screw diameter is dependent upon plate thickness and plate option. The screws will be available in both standard (locking) and lag design (non-locking) with a hex drive head feature. The plate screw holes are threaded and can accept both standard (locking) screws with threaded screw heads and lag design (non-locking) screws with non-threaded screw heads.

Available plates, screws, washers and instrumentation are packaged as a single system. The system instruments include guide wires, guide wire drill guide, drill bits, drill guides, tissue protectors, depth gauges, distractors, compressors, screwdriver shafts and driver handles. These instruments are used to facilitate the placement of the plates and screws.

Implant Materials

All Baby Gorilla®/Gorilla® Plates, Screws and Washers are made from Commercially Pure (CP Gr3, CP Gr4) Titanium (ASTM F67) and Titanium Alloy (ASTM F136). The instrumentation is made from medical grades of stainless steel, silicone and anodized aluminum.

Indications

The bone plates and bone screws of the Baby Gorilla®/Gorilla® Plating System are indicated for use in bone reconstruction/osteotomies, arthrodesis/joint fusion, and fracture repair/fracture fixation of the foot and ankle, appropriate for the size of the device.

System(s)	Indications	Intended Population(s)
Gorilla Plating System Plates and Bone Screws in Diameters: 2.7 mm, 3.5 mm, and 4.2 mm	The Gorilla plates and bone screws of the Gorilla Plating System are indicated for use in the foot and ankle for: - Bone Reconstruction/Osteotomy - Arthrodesis/Joint Fusion - Fracture Repair/Fracture Fixation	Adult and Pediatric Patients
Baby Gorilla Plating System Plates and Bone Screws in Diameters: 2.0 mm and 2.5 mm	The Baby Gorilla plates and bone screws of the Gorilla Plating System are indicated for use in the foot for: - Bone Reconstruction/Osteotomy - Arthrodesis/Joint Fusion - Fracture Repair/Fracture Fixation	Adult and Pediatric Patients
Silverback Plating System Plates and Bone Screws in Diameters: 4.5	The Silverback plates and bone screws of the Gorilla plating System are indicated for use in the ankle for: - Arthrodesis/joint fusion	Adult Patients

mm, 4.7 mm, 5.2 mm		
R3LEASE Stabilization System Solid Screws and Washers in 3.9 mm Diameter	The R3LEASE Stabilization Screws of the Gorilla Plating System are indicated for use in the ankle for: - Fracture repair/fracture fixation	Adult Patients
Non-locking Screws and Washers Diameters: 2.0 mm, 2.5 mm, 2.7 mm, 3.5 mm, 4.2 mm, 4.5 mm, 4.7 mm, 5.2 mm, and 5.5 mm	The Non-Locking Bone Screws and Washers of the Gorilla Plating System are indicated for use in the foot and ankle for: - Bone Reconstruction/Osteotomy - Arthrodesis/Joint Fusion - Fracture Repair/Fracture Fixation	Adult and Pediatric Patients

Contraindications

Use of the Baby Gorilla®/Gorilla® Plating System is contraindicated in cases of inflammation, cases of active or suspected sepsis / infection and osteomyelitis; or in patients with certain metabolic diseases.

All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Vascular, muscular or neurological pathologies that compromise the concerned extremity
- All concomitant pathologies that could affect the function of the implant
- Osteopathies with reduced bone substance that could affect the function of the implant
- 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
- Known or suspected sensitivity to metal
- Corpulence; an overweight or corpulent patient can strain the implant to such a degree that stabilization or implant failure can occur
- Whenever the use of the implant comes into conflict with the anatomical structures of physiological status

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- The presence of tumors
- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count

Potential Complications and Adverse Reactions

In any surgical procedure, the potential for complications and adverse reactions exists. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative wound infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- 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

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®, Inc. as soon as 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®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. 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 incorrect patient behavior.

Warnings and Precautions

- 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.
- Use of an undersized plate or screw in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments, guide wires and screws are to be treated as sharps.
- Patient risk as a result of the Baby Gorilla®/Gorilla® Plating System in the MR environment has been minimized.
- Do not use other manufacturer's instruments or implants in conjunction with the Baby Gorilla®/Gorilla® Plating System.
- Do not implant the instruments.

MR Safety Statement

The Baby Gorilla®/Gorilla® Plating System has been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration or image artifact in the MR environment. The safety of the Baby Gorilla®/Gorilla® Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Maintaining Device Effectiveness

- The surgeon should have specific training, experience, and thorough familiarity with the use of screw/plating systems.
- The surgeon must exercise reasonable judgment when deciding which plate and screw type to use for specific indications.
- The Baby Gorilla®/Gorilla® plates and screws are not intended to endure excessive abnormal functional stresses.
- The Baby Gorilla®/Gorilla® plates and screws are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique Baby Gorilla®/Gorilla® Plating 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 plates and screws prior to use, 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® Baby Gorilla®/Gorilla® Plating System implants may be provided sterile. If sterile, product has undergone gamma irradiation. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of device includes potential for patient to develop infection. Do not use implants after expiration date. Packages for implants should be intact upon receipt.

Implants 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 IMPLANT. Contact the manufacturer for further instructions. The implants should be opened using the aseptic technique described in P99-STR-1001. The implant should only be opened after the correct size has been determined. Once the seal of the product is broken, the product should not be re-sterilized.

Product should be stored in a clean and dry environment.

NON - STERILE PRODUCT

Product that is presented in a tray is provided non-sterile. All non-sterile implants and instruments should 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. For manual reusable instrument reprocessing instructions, refer to the Paragon 28®, Inc. *Instrument Reprocessing Instructions for Reusable Instruments* (P51-CLN-0001). For automatic processing instructions, refer to the Paragon 28®, Inc. *Automatic Reusable Instrument Reprocessing Instructions* document P99-CLN-1001. This is also available by calling (+1) (855) 786-2828.

Unless specifically labeled sterile, the implants and instruments 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, such as the KimGuard® Sterilization Wrap, is recommended. The following validated steam autoclave cycle is recommended:

Method	Cycle	Temperature	Exposure Time	Dry Time
Steam	Pre-Vacuum	270°F (132°C)	4 min.	30 min.

Instructions For Use

Only surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques should implant the Baby Gorilla®/Gorilla® Plating System. Refer to the Baby Gorilla® (P53-STG-1001) and Gorilla® Plating System Surgical Technique (P51-STG-1001) 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, (+1) (855) 786-2828

Screw and Plate Removal (If Necessary)

- Locate implant with intra-operative imaging.
- Palpate plate and head of screw removing surrounding soft tissue to gain maximum exposure.
- Engage screw head with appropriate driver and rotate counterclockwise until screw is removed from plate. Repeat as many times as necessary.

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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