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Englewood, CO 801
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BEFORE USING

OWING IMPORTANT INFORMATION

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

General Description
The 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 2.0-4.2mm 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 head.

OBSOLETE

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 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 For Use
The bone plates and bone screws of the Gorilla® Plating System are indicated for use in stabilization and fixation of fractures or osteotomies; intra and extra articular fractures, joint depression, and multi-fragmentary fractures; revision procedures, joint fusion and reconstruction of small bones of the toes, feet and ankles including the distal tibia, distal fibula, talus, and calcaneus. The system can be used in both adult and pediatric patients.

In addition, the non-locking, titanium alloy (Ti6Al4V ELI) screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges, appropriate for the size of the device.

Contraindications
Use of the 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 pathol… …mise the concerned extremity
- All concomitant pathologies … …he implant
- Osteopathies with r… … function of the implant
- Any … …acceptable risk … …operative trea…
- Know…
- Corpu… …nt patient can strain the implant to such a degre… …mplant failure can occur
- Whenev… …e implant comes into conflict with the anatomical structures … 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 exist. 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
- T… …bosis and embolism
- W… …ematoma and delayed wound healing
- T… …ary 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

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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.
- The Gorilla Plating System has not 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 Gorilla® Plating System in

the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

- **Do not use other manufacturer's instruments or implants in conjunction with the Gorilla® Plating System.**

Maintaining Device Effectiveness

- The surgeon should have specific training, experi… ugh familiarity with the use of screw/plating systems.
- The surgeon must exercise reason… ich plate and screw type to use for …
- The Gorilla® plate… abnormal functional …
- The Gor… only until osteogen…
- Failure to … stem instruments for every step of the … promise the integrity of the implanted de… e device failure and subsequent patient injury. Failed … quire re-operation and removal.
- Carefully inspe… 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.

Cleaning and Decontamination

All implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Paragon 28®, Inc. ***Gorilla® Plating System - Instrument Reprocessing Instructions for Reusable Instruments*** document P51-CLN-0001. This is also available by calling (888) 728-1888.

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

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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

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Please contact company for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.

Symbol Explanations

EC REP	**Authorized EU Representative**		**Manufacturer**
LOT	**Lot Number**	NON STERILE	**Non-sterile**
REF	**Item Number**		**e**
	Consult IFU		**tion**
	Keep Dry		

EC REP

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T

Obsolete

OBSOLETE

P51-IFU-1001 Rev A

4B Inverness Ct. E., Suite 280
Englewood, CO 80112
USA
(888) 728-1888
CE 0086

Gorilla® Plating System

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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
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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:

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- Thrombosis and embolism
- Wound hematoma and delayed wound healing
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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 Gorilla Plating System in the MR environment has been minimized.
- The 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 Gorilla® Plating System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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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 Gorilla® plates and screws are not intended to endure excessive abnormal functional stresses.
- The Gorilla® plates and screws are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique 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.

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Method	Cycle	Temperature	Exposure Time	Dry Time
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Instructions For Use

Surgeons, who are fully experienced in the use of such implants and the required specialized surgical techniques, should only implant the Gorilla® Plating System. Refer to the 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, (888) 728-1888.

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Symbol Explanations

EC REP	**Authorized EU Representative**		**Manufacturer**
LOT	**Lot Number**	NON STERILE	**Non-sterile**
REF	**Item Number**		**Do Not Reuse**
	Consult IFU	**R_x Only**	**USA: Prescription**
	Keep Dry		

EC REP Emergo Europe
Molenstraat 15, 2513 BH
The Hague, The Netherlands

P51-IFU-1001 Rev B

Gorilla® Plating System

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- Osteopathies with reduced bone substance that could affect the function of the implant
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- 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:

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- Increased leukocyte (WBC) count
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- Fractures resulting from unilateral joint loading
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	Consult IFU	**R_x Only**	USA: Prescription
	Keep Dry		

EC REP
Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
Netherlands

Australian Sponsor
Emergo Australia
Level 20, Tower II, Darling Park
201 Sussex St., Sydney, NSW 2000
Australia

CE 0086

Exclusively foot & ankle
Paragon 28®

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- 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

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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 Gorilla Plating System in the MR environment has been minimized.
- **Do not use other manufacturer's instruments or implants with the Gorilla® Plating System.**
- Do not implant the instruments.

MR Safety Statement
The Gorilla® Plating System has been evaluated for safety and compatibility in the MR environment. The Gorilla® Plating System has not been tested for heating, migration or image artifact in the MR environment. The safety of the 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 Gorilla® plates and screws are not intended to endure excessive abnormal functional stresses.
- The Gorilla® plates and screws are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique 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
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. Refer to the Paragon 28®, Inc. ***Instrument Reprocessing Instructions for Reusable Instruments*** (P20-CLN-0001). 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.

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Product should be stored in a clean and dry environment.

Instructions For Use
Surgeons, who are fully experienced in the use of such implants and the required specialized surgical techniques, should only implant the Gorilla® Plating System. Refer to the Gorilla® Plating System Surgical Technique P51-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, (+1) (855) 786-2828.

Screw and Plate Removal (If Necessary)

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- Engage screw head with appropriate driver and rotate counterclockwise until screw is removed from plate. Repeat as many times as necessary.

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Symbol Explanations

EC REP	Authorized EU Representative		Manufacturer
LOT	Lot Number	NON STERILE	Non-sterile
	Item Number		Do Not Reuse
	Consult IFU	**R_x Only**	USA: Prescription
	Keep Dry		Caution, consult accompanying documents
	Use-by date	STERILE R	Sterilized using irradiation
	Do not use if package is damaged		

EC REP
Emergo Europe
Prinsessegracht 20
2514 AP, The Hague
The Netherlands

Australian Sponsor
Emergo Australia
Level 20, Tower II, Darling Park
201 Sussex St., Sydney, NSW 2000
Australia

CE 0086

Exclusively foot & ankle

Paragon 28®

Baby Gorilla®/Gorilla® Plating System

4B Inverness Ct. E, Suite 280
Englewood, CO 80112
USA
(+1) (855) 786-2828

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

Implant Materials
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Indications
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In addition, the non-locking, titanium alloy (Ti6Al4V ELI) screws and washers are indicated for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair and fracture fixation of the foot and ankle, including the tibia, fibula, tarsus, metatarsals, and phalanges, appropriate for the size of the device.

Contraindications
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- 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
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Prinsessegracht 20
2514 AP, The Hague
Netherlands

Australian Sponsor
Emergo Australia
Level 20, Tower II, Darling Park
201 Sussex St., Sydney, NSW 2000
Australia

CE 0086

Baby Gorilla®/Gorilla® Plating System

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Please contact company for product inquiries, cleaning instructions and surgical techniques, or to report any adverse event.

Paragon 28, Inc.
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Englewood, CO 80112
USA
(+1) (855) 786-2828

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Emergo Europe
Prinsessegracht 20
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Australian Sponsor
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- 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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